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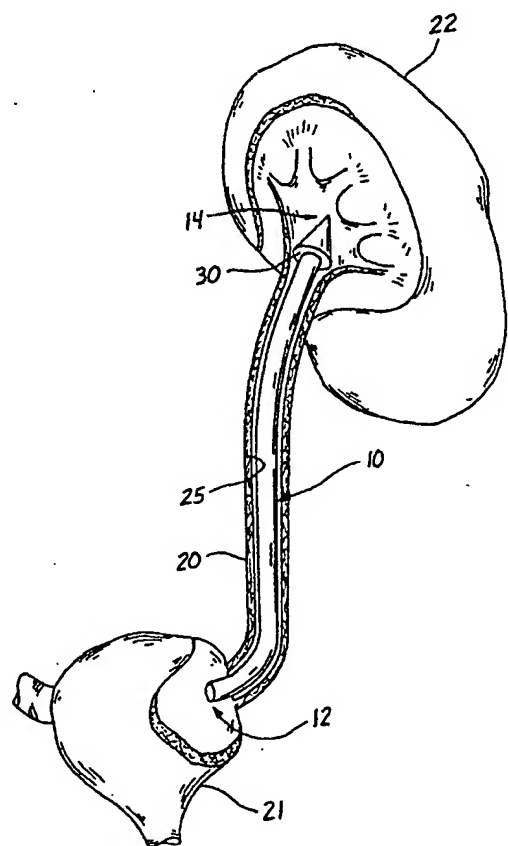
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: IMPROVED URETERAL STENT SYSTEM APPARATUS AND METHOD		
(57) Abstract		
<p>A stent (30) having an elongate tubular configuration is formed of a plurality of elongate elements (84) interwoven or braided to form a tubular configuration. The elements (84) may be relatively strong, and rigid, but movable relative to each other within the weave or braid in order to provide the stent with generally soft characteristics. The elements may be formed of different materials, such as an absorbent material permitting the stent to be doped with materials, such as drugs, and chemicals. Even the absorbency can be controlled, and varied to provide a predetermined time-release of the absorbent.</p> 		

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IMPROVED URETERAL STENT SYSTEM  
APPARATUS AND METHOD

5

Background of the Invention

Cross-Reference to Related Application

This application is a continuation-in-part of U.S. Patent Application Serial  
10 No. 09/109,355, filed on July 2, 1998, which is a continuation-in-part of U.S. Patent Application  
No. 08/806,337, filed on February 26, 1997, both of which are incorporated herein by reference.

Field of the Invention

The present invention relates generally to stents for use in supporting and  
15 maintaining an open lumen within a body passage or vessel and, more particularly, to stents  
configurable between large and small diameters.

Description of Related Art

Tubular prosthesis, which are commonly referred to as stents, are used to  
20 reinforce or strengthen body passages or vessels. Occluded, collapsed, or compromised body  
passages, such as blood vessels, esophagus, tracheas, gastrointestinal tracts, bile ducts, ureters,  
and urethras, can all benefit from stents. These body passages can become occluded, collapsed,  
or compromised from disease, trauma, or from specific surgical procedures upon the wall of the  
body passage.

25 Prior art stents typically comprise a length of plastic tubular material, having a  
number of side holes disposed along the length of the plastic tubular material. U.S. Patent  
Nos. 4,913,683; 4,643,716; 5,282,784; 4,957,479; 4,931,037; and 5,364,340 describe stents  
generally constructed in this manner. Each of these stents has a generally fixed diameter and,  
therefore, is non-responsive to the specific diameter of a vessel.

30 A prosthesis or stent capable of expanding to appropriate diameters, along the  
length of the stent, can provide advantages over fixed-diameter stents. Self-expanding stents are  
disclosed in U.S. Patent Nos. 5,026,377 and 5,078,720, both issued to Burton et al.; U.S. Patent  
No. 5,019,085 issued to Hillstead; U.S. Patent No. 4,969,458 issued to Wicktor; and U.S. Patent  
No. 5,041,126 issued to Gianturco. These self-expanding stents are typically held in a contracted

condition during insertion into the body passage or vessel and, after being positioned within the passage or vessel, released to expand fully. The stents of Wicktor and Gianturco comprise coiled or looped wires, which are unable to contact the entire surface of the interior wall of the affected vessel. The Hillstead stent incorporates a multiple-loop wire structure, which suffers from the same deficiencies associated with the Wicktor and Gianturco stents. U.S. Patent No. 5,507,767, issued to Maeda et al., discloses a self-expanding stent that employs a plurality of straight stainless steel wire sections, separating a plurality of bends, that may be adjusted and set to fit a particular anatomy or condition. U.S. Patent No. 5,476, 505 issued to Limon discloses a coiled stent for introduction into a body passage at a first diameter and subsequent expansion within the body passage to a second diameter. This coiled stent relies on a procedure for holding a coil in a tightly-wound condition during insertion of the coiled stent. U.S. Patent No. 5,409,019 issued to Wilk discloses a stent, which surrounds a balloon, so that the collapsed balloon, upon expansion, can expand the stent. U.S. Patent Nos. 5,078,720 and 5,026,377 issued to Burton et al. describe a combination of a self-expanding braided stent and an instrument for deployment or retraction of the stent. The instrument for deployment or retraction of the stent includes a tubular sleeve, which surrounds and compresses the braided stent. This surrounding tubular structure requires that an additional wall thickness, corresponding to a thickness of the tubular sleeve, be added to the device during placement. Consequently, a shortcoming of the Burton et al. invention is that the placement of the device is the time when the lowest profile or smallest diameter is required.

A need remains in the prior art for a prosthesis or stent which can be placed accurately into a low-profile or small-diameter condition and which can expand in diameter to a predictable size with a predictable pressure applied to an interior surface of the vessel wall. A need also exists in the prior art for a stent having a retention feature for maintaining the stent in a preferred position within the body passage. Additionally, a need exists in the prior art for a stent having a diameter, which is capable of responding and changing to the development of the lumen of the vessel or passage.

### Summary of the Invention

The stent of the present invention can be introduced into a body passage or vessel in a low-profile or small-diameter and, subsequently, expanded to a large diameter. The stent can be inserted into the body passage over a guidewire or small gauge catheter in the small

diameter configuration. After the guidewire or small gauge catheter is removed, the stent is transformed into the large diameter configuration, which stimulates the reactive nature of the body passage to thereby develop or maintain a patent lumen. The stent is able to provide maximum communication and flow of fluids from one surface of the stent to the other surface of the stent.

The stent of the present invention is formed of an elongate, flexible duct having a very thin wall and a preformed diameter, length, and shape. The stent is constructed of a woven tubular structure of multiple strands of elements. The woven tubular structure is thermally set to a predetermined diameter and length, so that the "at rest" or natural condition of the tubular structure is predictable. A retention or holding member can be formed at one or both of the ends of the stent. This retention member can be reduced in diameter or deformed or straightened for insertion into the body passage. The woven tubular structure provides a path for fluids to flow in and around the stent, while a patent lumen is being developed. The woven tubular structure allows the stent to be extended or stretched over a guidewire or other non-compressive member, to thereby reduce the diameter of the stent for insertion of the stent into a body passage.

The woven or braided stent can be formed from elements, such as polymers including polyester and metals such as Nitinol and titanium. These elements have a high-tensile strength and thereby resisting any breakage of the stent. Notwithstanding this high strength and structural integrity, the elements are generally movable relative to each other thereby providing the stent with an overall desirable, soft characteristic.

Various materials can be used to form the individual elements of the weave or braid. These materials can provide each element and the stent as a whole with considerably different characteristics at the operative site. The elements can be provided with absorbent characteristics facilitating a controlled release of drugs, chemicals, and other absorbents having medical characteristics.

In one aspect of the invention, a method of iteratively increasing a diameter of a lumen of a body passages includes the steps of inserting and moving a stent through the body passage to a desired location. At the operative site, the diameter of the stent is iteratively increased in a first iteration which provides the lumen with a first enlarged diameter and a second iteration which provides the lumen with a second enlarged diameter.

In another aspect of the invention, the stent is formed with a plurality of filaments disposed along an axis of the stent and providing the stent with an outer surface that is generally

cylindrical in configuration. A material is disposed relative to the filaments which maintains the filaments in a predetermined orientation at least during insertion of the stent into a body conduit. This material may initially provide the filaments with generally rigid properties in the presence of the material and generally flexible characteristics when the material is removed.

5 In a further aspect of the invention, a stent is provided with a body having first characteristics advantageous during insertion of the stent and second characteristics advantageous when the stent is operatively disposed in a body conduit. A material disposed relative to the body has first properties facilitating the first characteristics of the stent body during insertion and second properties facilitating the second characteristics of the stent body  
10 when operatively disposed. The material may be bio-absorbable, and impregnated into or coated on filaments forming the body.

In still a further aspect of the invention, the stent may include a first element with first a first absorbent providing the stent with properties dependent upon the medical characteristics of the first absorbent. A second element can be included in the stent and provided  
15 a second absorbent having absorption characteristics which differ from those of the first element.

The present invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in connection with the accompanying illustrative drawings.

#### Brief Description of the Drawings

20 Fig. 1 is a schematic view of the stent of the present invention directed to pass through a ureter between a kidney and a urinary bladder;

Fig. 2 is a side view of the stent in a radially expanded condition;

25 Fig. 3 is a side view of the stent in a radially compressed and longitudinally extended condition;

Fig. 4 is a side view of the stent of the present invention showing an introducer assembly;

Fig. 5 is a cut-away view of the stent positioned over an introducer assembly;

30 Fig. 6 is a cross-sectional view taken along the axis of both the stent and the introducer assembly;

Fig. 7 is an enlarged view of the retention member of the stent according to the present invention;

Fig. 8 is a view of one embodiment of the stent of the present invention having convoluted sections at opposing ends of the stent body;

5 Fig. 9 is a view of one embodiment of the stent of the present invention having convolutions along the length of the stent body;

Fig. 10 is a view of a material suitable for the construction of the stent;

Fig. 11 is a view of a forming tool or mandrel being used to form the stent of the present invention;

10 Fig. 12 illustrates the use of a mandrel or forming tool and the use of heat to set the material of the stent to a preferred embodiment;

Fig. 13 is a view of one embodiment of the stent of the present invention having a severable mid-section;

Fig. 14 is a view of one embodiment of the stent having a tether at one end;

15 Fig. 15 is an end view of the stent in an elongated condition within a body passage or vessel;

Fig. 16 is an end view of the stent in an expanded condition within a body passage or vessel;

20 Fig. 17 is an illustration of the forces applied outwardly from the axis of the stent and against the wall structure of the body passage or vessel;

Fig. 18 is a cut-away view of the stent within a body passage or vessel in an expanded condition;

Fig. 19 illustrates the relative length to diameter feature in an expanded condition of the stent;

25 Fig. 20 illustrates the relative length to diameter feature in an extended condition of the stent;

Fig. 21 illustrates the relative length to diameter feature in an intermediate condition of the stent;

30 Fig. 22 is a side elevation view of a stent formed of filaments and provided with an impregnation or a coating in a further embodiment of the invention;

Fig. 23 is a radial cross-section view taken along lines 23-23 of Fig. 22 and illustrating an embodiment wherein the stent has a central lumen;



Fig. 24 is a radial cross-section view similar to Fig. 23 and illustrating an embodiment wherein the stent has no central lumen;

Fig. 25 is a side elevation view of an embodiment similar to that of Fig. 22 wherein the coating provides sufficient column strength to facilitate insertion of the stent;

5 Fig. 26 is a radial cross-section view taken along lines 26-26 of Fig. 25 and illustrating the stent to have a central lumen;

Fig. 27 is a radial cross-section view similar to Fig. 26 and illustrating the stent with no central lumen;

10 Fig. 28 is a side elevation view similar to Fig. 22 wherein the impregnation or coating is bio-absorbable;

Fig. 29 is a radial cross-section view taken along lines 29-29 of Fig. 28 and illustrating the stent in a low-profile state prior to insertion;

Fig. 30 is a side-elevation view similar to Fig. 28 with the coating at least partially obliterated or absorbed to permit expansion of the stent to a high-profile state;

15 Fig. 31 is a radial cross-section view taken along lines 31-31 of Fig. 30;

Fig. 32 is a side elevation view similar to Fig. 22 wherein the filaments of the stent are disposed in a generally parallel, axial orientation;

Fig. 33 is a radial cross-section view taken along lines 33-33 of Fig. 32 and illustrating the stent to have a central lumen;

20 Fig. 34 is a radial cross-section view similar to Fig. 33 and illustrating a stent with no central lumen;

Fig. 35 is a side elevation view similar to Fig. 22 wherein the filaments are spiraled in a rope configuration;

25 Fig. 36 is a radial cross-section view taken along lines 36-36 of Fig. 35 and illustrating the stent with a central lumen;

Fig. 37 is a radial cross-section view similar to Fig. 36 and illustrating the stent with no central lumen;

Fig. 38 is a perspective view of a helical stent illustrated in a low-profile state;

30 Fig. 39 is a perspective view of the helical stent of Fig. 38 in a natural, high-profile state;

Fig. 40 is a perspective view of a stent having coiled ends and illustrated in a stretch configuration;

Fig. 41 is a perspective view of the coil-end stent of Fig. 40 illustrated in a natural configuration;

Fig. 42 is a side-elevation view of an additional embodiment of the invention similar to that of Fig. 41;

5 Fig. 43 is a side-elevation view of a positioner adapted for use with the embodiment of Fig. 42;

Fig. 44 is a side-elevation view of the stent of Fig. 42 disposed for insertion in a low-profile state on the positioner of Fig. 43;

10 Figs. 45-47 illustrate steps in a preferred method for insertion of the stent of Fig. 42;

Fig. 45 is a schematic view illustrating insertion of the stent combination of Fig. 44 over a guidewire;

Fig. 46 is a schematic view illustrating the step of removing the positioner;

15 Fig. 47 is a schematic view of the ureter illustrating the step of removing the guidewire;

Fig. 48 is a side-elevation view illustrating the step of covering the stent and positioner combination with an oversheath;

Fig. 49 is a side-elevation view illustrating the positioner stent and oversheath in combination;

20 Fig. 50 is a side-elevation view of a further embodiment of the invention, including radiopaque markers;

Fig. 51 is a side-elevation view of a further embodiment of the invention, including a tether;

25 Fig. 52 is a side-elevation view of an additional embodiment, including a non-mesh pigtail anchor;

Fig. 53 is a side-elevation view of a further embodiment having an anchor with a spherical shape;

Fig. 54 is a side-elevation view of a further embodiment having multiple spherical mesh anchors;

30 Fig. 55 is a side-elevation view of a further embodiment with a preferred body portion of the stent;

Fig. 56 is a side-elevation view of a further embodiment, including the body portion with a solid cylindrical element;

Fig. 57 is a side-elevation view of a further embodiment, including a mesh anchor and a non-mesh body portion;

5 Fig. 58 is a side-elevation view of a further embodiment disposed in situ and having a body portion with an aforeshortened link;

Fig. 59 is a further embodiment of the invention having a filament tether; and

Fig. 60 is a side-elevation view of a further embodiment free of any anchor portions.

10

#### Detailed Description of the Presently Preferred Embodiments

Turning to Figure 1, a stent or prosthesis 30 according to the presently preferred embodiment is illustrated having a proximal tube end 32 and a distal tube end 34. The stent body 36 is shown within a body passage or vessel 38, such as a ureter. The stent body 36 extends within the ureter 38 between a kidney 40 and a urinary bladder 42. The stent body 36 of the present invention is sized and configured to exert a compressive force against the interior surface 45 of the body passage 38. In the presently preferred embodiment, the stent 30 comprises a retention member 48 at the distal tube end 34. The stent 30 of the embodiment shown in Figure 1 comprises a ureteral stent, which is adapted for developing or maintaining a patent lumen in the ureter 38 between the kidney 40 and the urinary bladder 42. The stent 30 facilitates passage of fluid in, through, and around the stent body 36 from the kidney 40 to the urinary bladder 42.

25 The stent of the present invention preferably comprises a woven material, which can be elongated and contracted. Figure 2 is a side view of the stent 30 in a contracted, radially expanded condition. The condition illustrated in Figure 2 corresponds to an "at rest" or natural condition of the stent 30. The lumen of the stent body 36 is fully developed along the length of the stent body 36, narrowing only at the distal tube end 34. The retention member 48, which forms a cuff or enlargement sized and configured to engage a portion of an organ or passage, has an enlarged diameter in the natural condition shown in Figure 2. The retention member 48 assists in maintaining the stent 30 within the body passage 38, as illustrated in Figure 1, for example.

30

Figure 3 illustrates the stent 30 in a stretched, radially compressed and longitudinally extended condition. The stent body 36 is preferably reduced in diameter in order to facilitate placement of the stent 30 into a body passage 38. When the stent 30 is stretched along its axis, the diameters of the stent body 36 and the retention member 48 are significantly  
5 reduced to facilitate a low-profile configuration for insertion into the body passage 38. As presently embodied, the stent 30 is placed into the low-profile condition by application of a tensile force applied to both the proximal tube end 32 and the distal tube end 34.

As illustrated in Figure 4, a compression sleeve 60, having a proximal end 62 and a distal end 64 (Figure 5), can be inserted into a lumen of the stent 30. The compression  
10 sleeve 60 is preferably inserted into the lumen of the stent 30, until the distal end 64 of the compression sleeve 60 contacts the distal tube end 34 of the stent 30. After this placement, the proximal tube end 32 of the stent 30 can be drawn proximally, relative to the compression sleeve 60, to thereby facilitate elongation of the stent 30. In other words, since the distal end of the compression sleeve 60 cannot pass through the narrow aperture of the distal tube end 34,  
15 movement of the proximal tube end 32 proximally will lengthen the stent 30. As the stent 30 increases in length, the diameter of the stent 30 decreases. The reduced diameter of the stent 30 facilitates a less-intrusive insertion of the assembly into a body passage 38.

A guidewire 70, having a proximal end 72 and a distal end 74, may be placed within the compression sleeve 60. The guidewire 70 provides a means for establishing a track,  
20 so that the stent 30 and compression sleeve 60 may be advanced along the guidewire 70 to a desired location within the body passage 38, with the stent 30 in an elongated configuration. After the stent 30 is moved to the desired location, the proximal tube end 32 of the stent 30 is released or relaxed, to thereby allow the proximal tube end 32 to move distally, resulting in an enlargement of the diameter of the stent 30. According to the presently preferred method of  
25 insertion, the guidewire 70 is placed within the body passage 38, and the stent 30 is then placed over the proximal end 72 of the guidewire 70. Next, the compression sleeve 60 is placed over the proximal end 72 of the guidewire 70 and into the stent body 36.

Figure 5 illustrates a cut-away view of the stent 30 positioned over both the compression sleeve 60 and the guidewire 70, and Figure 6 illustrates a cross-sectional view of  
30 the assembly shown in Figure 5. As illustrated in Figures 5 and 6, the compression sleeve 60 fits between the stent 30 and the guidewire 70. The opening at the distal end 34 of the stent 30 does not permit the distal end 64 of the compression sleeve 60 to pass through. This configuration

permits the stent 30 to be stretched lengthwise, as the proximal end 32 of the stent 30 is extended proximally along the surface of the compression sleeve 60. At full extension, the profile of the stent 30 exceeds the outside diameter of the compression sleeve 60 by the thickness of the wall of the stent body 36. This extended/compressed relationship exists as long as a holding force is maintained between the proximal end 32 of the stent 30 and the compression sleeve 60. When this force is removed, the stent 30 assumes an "at rest" or expanded profile.

Figure 7 illustrates an enlarged view of the retention member 48 of the presently preferred embodiment. The retention member 48 preferably comprises an enlarged diameter capable of engaging a portion within a vessel or organ, to thereby prevent the stent 30 from migrating or slipping from a desired position or location within the vessel or organ. The distal ring 81 of the retention member 48 is preferably sized and configured to prevent the compression sleeve 60 (Figure 5) from passing therethrough. The distal ring 81 preferably comprises a thermally fused or melted portion of material fibers 84 from which the stent 30 is woven. The distal ring 81, however, may be formed in other ways and/or comprise other materials. In the presently preferred embodiment, the retention member 48 comprises the shape of a cone 87 having a small diameter portion 89 distally located from a large diameter portion 92. The retention member 48 preferably comprises a substantially folded lip section 95 and a substantially folded angular portion 98 providing a transition between the stent body 36 and the retention member 48.

Figures 8 and 9 illustrate stents 30 having series of convolutions 100, 102, and 104 formed along the stent bodies 48. These convolutions 100, 102, 104 can operate to add strength to the retention members 48 and 107. The convolutions 100, 102, 104 also provide additional strength to the stent bodies 36 for resisting compression in much the same way as corrugated tubing resists kinking and compression. Additionally, the convolutions 100, 102, 104 assist in providing traction within the lumen of a body passage 38 and are sized and configured to be reduced in profile in the same manner as the stent body 36 by the application of traction or tension upon the stent body 36.

As illustrated in Figure 10, the stent 30 is formed from an initial woven tubular structure 111, which preferably comprises a thermoplastic material or mesh. This construction begins by weaving or braiding a plurality of individual or groups of individual fibers or elements 84 into a tubular stent body 36. Desired characteristics may be developed within this construction for providing ratios of expansion to extension, as is known in the art.

After the woven tubular structure 111 is generated, the woven tubular structure 111 is placed onto a forming tool or mandrel 113 having a proximal end 115 and a distal end 117. The mandrel 113 serves as a form in setting the thermoplastic material of the woven tubular structure 111. In the presently preferred embodiment, the forming tool 113  
5 comprises a first diameter near the proximal end 115 and a second diameter near the distal end 117. The first diameter represents the desired maximum deployed or expanded diameter of the stent body 36 when the stent body 36 is within a body passage or vessel 38, and the second diameter corresponds to the diameter of a conventional guidewire 70 (Figure 6) but compression sleeve 60 (Figure 6).

10 Alternatively, the stent 30 can be formed of metal material such as Nitinol (a trademark of Raychem, Inc.) or a titanium. Nitinol is well-known for its heatset properties which would enable it to function in the manner previously discussed. Titanium has excellent biocompatibility features which might make it a preferred material in a particular environment.

The woven tubular structure 111 of the stent 30 is folded proximally upon the  
15 forming tool 113 to thereby form the retention member 48. As shown in Figure 12, the forming tool 113 and the woven tubular structure 111 are next exposed to radiation 121 from a heat source or an oven preferably at a temperature sufficient to set the material of the woven tubular structure 111 to the preferred condition. In the presently preferred embodiment, the material comprises a thermoplastic, such as a polyester or nylon, since these materials allow for the  
20 development of a permanent, thermally-set condition. Additionally, the distal tube end 34 and the distal ring 81 are preferably fused or melted to form a solid ring or collar which provides support for the compression sleeve 60. As a secondary operation, a proximal portion 123 of the stent body 36 may be coated with an elastomeric material to thereby provide stability at the proximal portion 123.

25 Figure 13 illustrates a stent 30 having a tether 130 attached or formed at the proximal tube end 32 for assisting in the placement or the removal of the stent 30 from a body passage 38.

Figure 14 illustrates a stent having a first retention member 48 and a second retention member 136 located at an end opposite from the first retention member 48. The stent  
30 having the two retention members 48, 136 may be used as is or, alternatively, the stent may be cut at a preferred location 138 to form two individual stents 140 and 142.

Figure 15 illustrates an end view of the stent 30 of the presently preferred embodiment within a body passage 38. The stent 30 is illustrated in an extended, small diameter condition over both the compression sleeve 60 and the guidewire 70. Figures 16 and 17 illustrate the stent 30 in a large-diameter relaxed state. The guidewire 70 and the compression sleeve 60 may be removed at this time. The stent body 36 exerts a constant outward pressure 151 upon the interior surface 45 of the body passage 38. This outwardly directed radial pressure, along with the naturally occurring tendency for the intimal tissue to move away from a foreign body, combines to enlarge and/or maintain the lumen of the body passage 20.

An enlarged view of a body passage 38 is provided in Figure 18 with a stent 30 of the presently preferred embodiment fully extended within the lumen of the body passage 38. The individual fibers or groups of fibers 84 are spaced apart to thereby allow for the flow 155 of fluid through and around the stent body 36 as the stent body 36 applies outward pressure to the interior surface 45 of the body passage 38.

The relationship between the length and the diameter of the stent 30 of the present invention is illustrated in Figures 19-21. The stent 30 in the "at rest" or natural, relaxed condition is illustrated in Figure 19 with a fully expanded, maximum diameter 172. Due to the naturally occurring relationship of the fibers or elements 84 of a woven or braided tubular structure 111 (Figure 10), a change in length 170 will accompany any change in diameter 172. Conversely, any change in length 170 precipitates a commensurate change in diameter 172. The present invention harnesses this relationship to facilitate the placement, maintenance, and removal of the stent 30. As presently embodied, the length 174 and the diameter 176 of the retention member 48 change somewhat proportionally to changes in the length 170 and diameter 172 of the stent body 36.

With reference to Figure 20, as the stent 30 is stretched or extended in length 180, 181, the diameters 182 of the stent body 36 and the diameter 186 of the retention member 48 are both reduced. Upon removal or relaxation of the stretching or extending force, the stent 30 attempts to assume an original "thermally set" or natural condition within the body passage. Accordingly, the length 190 and the diameter 192 increase from the length 180 and the diameter 182 of Figure 20, as illustrated in Figure 21. Similarly, the length 191 and the diameter 196 of the retention member 48 increase. The increased diameters 192, 196 exert radially outwardly directed forces upon any resistive structure. As the diameters 192, 196

increase, the lumen within the body passage 38 will also increase, thereby facilitating further increases in the diameters 192, 196.

The intimal tissue of the body passage 38 responds to the presence of the braided material by moving away from the stent 30. Thus, the lumen of the body passage 38 enlarges in response to the presence of the stent 30. As the lumen enlarges, the self-expanding stent 30 follows the inner surface of the body passage 38 and continues to expand. This, in turn, stimulates further enlargement of the lumen of the body passage 38. This expansion-response of the stent 30 and body passage 38 continues until a maximum lumen diameter is achieved.

The expansion-response reaction of the body passage 38 is believed to be a reaction to the members of the braided material and the motion of these members within the body passage 38, especially when the body passage comprises a ureter. The expansion-response reaction may also be attributed generally to a foreign body reaction within the body passage 38. In the particular case of a ureter, it is believed that the irritation from the braided or woven members causes this response.

A further embodiment of the invention is illustrated in Figure 22 wherein elements of similar structure are designated by the same reference numeral followed by the lower case letter "a." Thus, stent 30a includes a plurality of fibers or filaments 84a which extend generally along an axis 200 between proximal end 32a and distal end 34a.

The filaments 84a may be oriented to provide the stent 30a with a central lumen 203, best illustrated in Figure 23. Alternatively, the stent 30a may be formed with a generally solid configuration, free of any central lumen, as illustrated in Figure 24. In combination these filaments 84a provide the stent 30a with a generally cylindrical outer surface 202. In the embodiment of Figure 22, the stent 30a is also provided with a material 204 which at least partially impregnates and/or coats the filaments 84a.

The filaments 84a, together with the material 204, can provide the stent 30a with a variety of characteristics. For example, in Figure 22, the filaments 84a have a generally rigid configuration when coated or impregnated with the material 204. However, in the absence of the material 204, the filaments 84a may be more limp and flexible. Taking advantage of these characteristics of the filaments 84a, the material 204 can be chosen with bio-absorbable characteristics. When the material 204 is disposed relative to the filaments 84a, the stent 30a has the generally rigid characteristics which facilitate its insertion into the body passage or conduit. However, once the stent 30a is operatively disposed within the conduit, the material 204 is at



least partially absorbed or otherwise removed, leaving the stent 30a with the generally flexible characteristics and thereby facilitating the fluid-flow properties of the stent.

In the embodiment of Figure 25, elements of similar structure are designated by the same reference numerals followed by the lower case letter "b." In this case, the material 204b is coated on, impregnated into, or otherwise disposed relative to the filaments 84b. As illustrated in Figures 26 and 27, the stent 30b may be provided with a central lumen 203b or, alternatively, provided with a generally solid structure, respectively. The material 204b is of particular interest in this embodiment as it is chosen to provide the stent 30b with a generally fixed, predetermined length and diameter. Nevertheless, the material 204b may be very flexible. In this case, the stent facilitates fluid flow between its ends 32b and 34b in a "wicking" action.

Another embodiment is illustrated in Figure 28 wherein like elements of structure are designated by the same reference numeral followed by the lower case letter "c." In this case, the characteristics chosen for the filaments 84c and the material 204c are of particular interest. For example, the filaments 84c can be made from a material having expansion characteristics which cause the stent 30c to automatically move from a low-profile state to a high-profile state. The material 204c can be chosen with bio-absorbable characteristics whereby the stent 30c is maintained in its low-profile state in the presence of the material 204c, as illustrated in Figure 28. In this low-profile state, the stent 30c may have a generally solid configuration as illustrated in the radial cross-section view of Figure 29.

In this embodiment, it is the properties of the material 204c which initially hold the filaments 84c in the low-profile state. However, after the stent 30c is inserted into the body conduit, these bio-absorbable characteristics cause the material 204c to be absorbed, ablated, or otherwise at least partially removed from the filaments 84c. This permits the filaments 84c to expand to the high-profile state as illustrated in Figure 30. In this view, and the radial cross-section view of Figure 31, a dotted line 206 illustrates the material 204c in a partially removed state permitting automatic expansion of the filaments 84c. In this embodiment, the bio-absorbable material 204 includes polyglycolic acid.

It can be seen that in several of these embodiments, it is the combination of characteristics present in the filaments 84 and the material 204 which are relied on to provide the stent 10 with different properties facilitating insertion on the one hand and operative disposition on the other hand. For example, in the embodiment of Figure 28, the filaments 84c have first characteristics, such as a low-profile, and second characteristics, such as a high-profile.

Similarly, the material 204 has first characteristics, such as an integrous coating on the outer surface 202c, and second characteristics, such as a weakened or absorbable coating. In combination, the first characteristics of the material 204 facilitates the first characteristics of the filaments 84 while inhibiting the second characteristics of the filaments 84. This facilitates insertion of the stent 10. When the stent 10 is operatively disposed, the second characteristics of the material 204 facilitate the second characteristics of the filaments 84 while inhibiting the first characteristics of the filaments 84. This provides the stent 30c with the best performance when disposed at the operative site.

The embodiments of Figures 32, 35, and 38 include elements similar to those previously discussed which are designated by the same reference numerals followed by the lower case letters "d", "e", and "f", respectively. These embodiments are illustrative of the fact that the filaments 84 can be disposed in any relative configuration typically providing the stent 10 with an elongate, cylindrical configuration. For example, the filaments 84c in Figure 28 may be woven whereas the filaments 84d in Figure 32 are generally straight and parallel to the axis 200d. These filaments 84d can be oriented to provide the stent 10d with a central lumen 203d as illustrated in Figure 33, or a generally solid configuration as illustrated in Figure 34. In this embodiment, the material 204d is shown to be impregnated into the filaments 84d.

In a further orientation, illustrated in Figure 35, the filaments 84e are spiraled in a rope configuration. This embodiment may also be formed with a central lumen 203e as illustrated in Figure 36, or a generally solid configuration as illustrated in Figure 37.

A further embodiment providing a spiraled configuration is illustrated in Figure 8 wherein the stent 30f is formed as a helix or spring. With this configuration, the stent 30f may have a single element 84f or a polarity of elements each forming a helical spring. Where multiple springs are contemplated, the elements 84f may be disposed one within the other and may also be spiraled in different directions.

In Figure 38, the stent 30f is illustrated in a low-profile state which is achieved by separating the ends 32f and 34f. This low-profile state facilitates insertion of the stent 30f. When the ends 32f and 34f are released, the helix is free to return to its normal high-profile state, as illustrated in Figure 39. In this embodiment, the desired freedom of movement of the filament 84f between its ends 32f and 34f is facilitated by the convolutions of the helical spring which are free to move relative to each other. Coils 205 and 206 can be formed at the ends 32f and 34f as illustrated in Figure 39. These coils 205, 206, which automatically form when the

stent 30f is in its natural state, tend to anchor the stent 30f in its operative position. Of course, when the stent 30f is initially inserted, it is desirable that these coils 205 and 206 straighten along the axis of the stent as illustrated in Figure 38. In this stretched configuration, the stent 30f can be easily inserted into the conduit and then released to form its untensioned, natural state as  
5 illustrated in Figure 39.

These same coils 205 and 206 can be formed in the embodiment illustrated in Figures 40 and 41 wherein similar elements are designated by the same reference numerals followed by the lower-case letter "g". In this embodiment, the stent 30g is formed from braided or woven elements 84g which extend between the stent ends 32g and 34g. In this embodiment,  
10 the coils 205g and 206g can be formed in the ends of the stent 30g as previously discussed. These coils 205g and 206g can be axially oriented by tensioning the stent 30g as illustrated in Figure 40. This facilitates insertion of the stent 30g which returns to its natural state as illustrated in Figure 41 when tension is removed at the operative site.

The stent 30g is further illustrated in Figure 42 to include a body portion 210 with  
15 a proximal end 212 and a distal end 214. This body portion 210 has a tubular configuration with a diameter such as one-eighth inch to one-quarter inch. Extending from the distal end 214, an anchor portion 216 can be provided in a contiguous relationship with the body portion 210. This anchor portion 216 also has a tubular configuration and is connected at one of its ends to the distal end 214 and is provided at its other end with a constriction 218. The anchor portion 216  
20 may also have a tubular configuration and may be formed as an extension of the mesh defining the body portion 210. A similar anchor portion 221 can be coupled to the proximal end 212, but it is preferably formed without a constriction.

As in previous embodiments, the filaments forming the mesh of the stent 30g can be heatset so that, at rest, the stent 30g tends toward the general shape illustrated in Figure 42.  
25 This shape includes the enlarged body portion 210, as well as the pigtail configuration of the anchor portions 216 and 221. With these heatset properties, the stent 30g is particularly adapted for insertion using a positioner 223 such as that illustrated in Figure 43. This positioner 223 preferably has the configuration of a tube with an interior lumen 225. The positioner 223 can be formed of flexible or semi-rigid material, and provided with a generally straight, but bendable,  
30 configuration.

In operation, the positioner 223 is inserted into the anchor portion 221 at the proximal end of the stent 30g. It is moved through the stent 30g until it abuts the

constriction 218 at the end of the anchor portion 216, as illustrated in Figure 44. In this configuration, the stent 30g is maintained in a generally straight configuration and stretched to a low-profile state facilitating insertion.

Operative disposition of the stent 30g is best described with reference to  
5 Figures 45-47. In these figures, the ureter 38g is illustrated between the bladder 42g and the kidney 40g. Initially, a guidewire 230 can be introduced through the bladder 42g and into the kidney 40g. With the positioner 223 operatively disposed in the stent 30g, as illustrated in Figure 44, this combination can be introduced over the guidewire 230g, as illustrated in Figure 45. In accordance with this method, the guidewire tends to guide the positioner 223 and  
10 stent 30g through the tortuous path of the ureter 38g.

Once the stent 30g is appropriately positioned with the body portion 210 disposed in the ureter 30g, the positioner 223 can be withdrawn leaving the stent 30g and the guidewire 230, as illustrated in Figure 46. The guidewire 230 can then be moved from the stent 30g leaving the stent 30g operatively disposed with the body portion 210 in the ureter 38g,  
15 the anchor portion 216 in the kidney 40g, and the anchor portion 221 in the bladder 42g. In the absence of either the positioner 223, or the guidewire 230, the heatset characteristics will cause the ends of the stent 30g to curl or coil into a pigtail configuration, as illustrated in Figure 47. These same heatset characteristics will cause the body portion 210 of the stent 30g to expand, thereby irritating the walls of the ureter 38g and causing them to further expand the diameter of  
20 the ureter 38g.

As illustrated in Figure 48, a second pusher 235 can be provided to abut the proximal end of the stent which is mounted on the first positioner 223. The second positioner 235 can aid in releasing the stent 30g from the first positioner 223 as it is withdrawn through the stent.

25 An oversheath 236, but illustrated in Figure 49, can be provided to cover the combination of the positioner 223 and stent 30g. When operatively disposed, the oversheath 236 covers at least a portion of the stent 30g, as illustrated in Figure 49. The placement of radiopaque markers 238 and 241 on the stent 30g and sheath 236, respectively, can facilitate maintenance of this operative disposition. When the oversheath 236 is in place, the mesh  
30 configuration of the stent 30g is replaced with a smooth outer surface of the oversheath 236 to facilitate introduction of the stent into the ureter 38g.

Other radiopaque markers can be provided on a stent 30g, as illustrated in Figure 50. In addition to the marker 238 at the end of the distal anchor portion 216, a similar radiopaque marker 243 can be provided at the end of the proximal anchor portion 221. A verification marker 245 can be provided along the distal anchor portion 216 in proximity to the body portion 210. Since the mesh of the stent 30g is generally not visible under fluoroscopy, movement of the marker 238 into proximity with the verification marker 245 will provide an indication that the loop, coil, or pigtail of the anchor portion 216 has formed.

Figure 51 illustrates a further embodiment of the stent wherein elements of similar structure are designated by the same reference numerals followed by the lower case letter "h". In this particular embodiment, there is no anchor portion 221, but rather a generally straight tether which is attached to the proximal end of the body portion 210h. In those case where an anchor is not required in the bladder 42g, the tether 245 will merely provide a connection to the body portion 210 to ultimately facilitate removal of the stent 30h.

A further embodiment of the stent 30i is illustrated in Figure 52 wherein the anchor portion 216i is formed from a material such as a silicon, urethane, or other elastomer, but is not provided with the mesh configuration. Where the anchor portion 216i is not formed integral with the body portion 210i, these elements 216i and 210i must be coupled at a junction 247 by other means such as an adhesive or a mechanical interlock. In this embodiment of Figure 52, the junction 247 can be formed with the restriction 218i so that the positioner, such as the positioner 223 of Figure 24, extends only to this junction 247. In this case, the guidewire 230i is relied on to straighten the anchor 216i during insertion. The positioner 223i functions to push the anchor portions 216i, and to pull the remainder of the stent 30i distal of the junction 247.

Further embodiments of the invention are illustrated in the side-elevation views of Figures 53, 54, 55, 56, 57, 58, 59, and 60. In these views, elements similar to those previously discussed are designated by the same reference numerals followed by the lower-case letters j, k, l, m, n, o, p, and q, respectively. For example, in the embodiment of Figure 53, the stent is designated by the reference numeral 30j. In this embodiment, the body portion 210j and the tether 245j can be similar to those previously discussed. A distal anchor 250 can be heatset in the general configuration of a sphere 252 having a diameter such as one-half inch to one inch in certain preferred embodiments. The sphere 252 can be formed of any of the materials previously

discussed, but in a preferred embodiment is formed of a mesh material which is integral with the mesh of the body portion 210j.

Since most of the patient discomfort associated with stents results from the anchors in the bladder 42 and kidney 40, the spherical anchor 250 offers considerable advantage to this embodiment of the invention. The only contact with the kidney in this case is along a hemispherical surface 254 which contacts the body portion 210j. This advantage is achieved without sacrificing the advantages of previous embodiments which provide for use of a positioner, such as the positioner 223 of Figure 24. Tensioning the stent 30j on such a positioner causes the sphere 252 to collapse to a cylindrical, low-profile configuration facilitating insertion. Upon removal of the positioner 223 and guidewire 230 (Figures 46 and 47), the heatset mesh automatically expands to form the spherical anchor 250.

The embodiment of Figure 54 illustrates that the stent 30k can be formed not only with the distal spherical anchor 250k, but also a proximal spherical anchor 256.

In the embodiment of Figure 55, the stent 30l includes pigtail anchors 216l and 221l of the type previously discussed. In this embodiment, the body portion 210l differs from the generally cylindrical configuration previously discussed. In this case, the body portion 210l includes a central portion 261 which is heatset to a generally cylindrical configuration. The body portion 210l also includes tapered portions 263 and 265 which are disposed at opposite ends of the central portion 261. The tapered portion 263 is connected between the central portion 261 and the distal anchor 216l, while the proximal tapered portion 265 is connected between the central portion 261 and the proximal end 221l. The distal taper 263 in this embodiment is provided with a relatively large taper angle making this portion 263 relatively short compared to the proximal tapered portion 265 where the taper angle is relatively small. In many of the other aspects of the stent 30l, features are similar to those previously discussed which provide for low-profile insertion using a positioner, such as the positioner 223 of Figure 24.

A further embodiment of the stent is illustrated in Figure 56 and designated by the reference numeral 30m. This embodiment includes the mesh pigtail 216m, as well as a mesh body portion 210m with tapered portions 263m and 265m. In this embodiment, the body portion 210m also includes a cylindrical portion 267 which is formed of a solid material and joined to the mesh material of the tapered portion 265m at a junction 269. The cylindrical portion 267 can be formed of silicone, urethane, or other elastomer. This material can be joined

to the mesh at the junction 269 by adhesive or by a mechanical, heatset interlock between the fibers of the mesh and the solid material of the cylinder 267.

The embodiment of Figure 57 is similar to that of Figure 56 in that it includes the cylinder 267n and proximal anchor 221n. In this embodiment, the mesh body portion 210n has  
5 been eliminated, but the distal mesh spherical anchor 252 has been retained.

The stent 30o illustrated in Figure 58 combines the spherical mesh anchor 250o of the Figure 53 embodiment, as well as the body portion 210o and tether 245o associated with the Figure 51 embodiment. In this case, it is noted that the body portion 210 has a length which is shorter than the length of the ureter 38. Realizing that the incision is made in the upper portions  
10 of the ureter 38o, and that the features of the stent 30o are most appreciated in the vicinity of the incision, the body portion 210o of this embodiment is limited to that region. In a preferred embodiment, the shortened length of the body portion 210o is about one-half the length of the ureter 38o. Only the tether 245o extends through the proximal end of the ureter 38o and into the bladder 42o. The stent 30p illustrated in Figure 59 is similar to that illustrated in Figure 58,  
15 except that the tether 248o is formed as a solid shaft, string, or filament 270.

A further embodiment of the invention is illustrated in Figure 60, where the stent 30q is free of any anchors such as the distal anchor 216 or proximal anchor 221 of the embodiments previously discussed. This embodiment can still be formed of a mesh material and provided with a body portion 210q terminating in a distal taper 272 and a proximal taper 274. At  
20 the distal end, the constriction 218q can be formed to facilitate insertion with a positioner, such as the positioner 223 of Figure 24.

It can be seen from the foregoing discussion that various embodiments of this concept include at least one filament which is formed from a relatively strong material such as polyester. While this material may be strong and somewhat rigid, the stent 30 is provided with  
25 relatively soft characteristics due to the configuration applied to the filaments 84. Movement of the filaments 84 between the ends 32 and 34 of the stent 30 is desired not only to facilitate this soft characteristic, but also to "irritate" the wall of the conduit. This causes the conduit wall to move away from the stent 30 thereby increasing the patency of the conduit. In some cases, the stent 30 is provided with characteristics to naturally move toward a larger diameter. With these  
30 properties, the stent 30 effectively chases the wall radially outwardly to further increase the patency of the conduit.

Between the ends 32 and 34 of the stent 30, the elements 84 are free to move relative to each other between a low-profile state facilitating insertion and a high-profile state facilitating conduit patency. This relative movement of the elements 84 not only facilitates the soft characteristics preferred for the stent 30, but also results in the desired irritation of the conduit wall.

Although it is contemplated that most embodiments of the stent 30 will include elements 84 formed of the same material, this may not always be the case. In some instances, it may be desirable to form the elements 84 from different materials to provide the overall stent 30 with properties representative of each of the materials. For example, some of the elements 84 may be formed from a polyester material providing the stent with a relatively high tensile strength. Other elements may be formed of an absorbent material which can be saturated, for example, with an antibiotic, an anesthetic, an analgesic, a material to control encrustation, a radiopaque material, or any other material having medical characteristics.

The impregnation or coating of the elements 84 with drugs or chemicals offers particular advantages. For example, some procedures require such chemicals or drugs to be administered at a specific site within a body passage. When these drugs or chemicals are administered systemically, there can be concomitant and adverse side-effects. When it is desirable to administer medications, drugs, or chemicals, particularly those that are highly concentrated or powerful, a system for localizing the effect to a specific site can be particularly advantageous in avoiding the side-effects of systemic administration. To this end, an intraluminal device for local administration of the medications, drugs, or chemicals is contemplated by the present invention.

More specifically, a stent 30 having properties for absorbing and subsequently delivering or releasing a chemical or a drug is foreseen. When the stent 30 is provided with a woven or braided tubular structure, it can be inserted into a body passage for the purpose of increasing patency of that passage. The stent can be constructed solely of mono-filament fibers or a rigid polymer, as previously discussed. These fibers are generally non-absorbent. However, in an alternate embodiment, at least one of the elements can be formed of cotton, dacron, or other absorbent material. These absorbent elements can be woven with the mono-filaments elements, in a predetermined ratio facilitating delivery of an absorbed chemical, drug, or medication. The stent can then be soaked, wiped, or doped with the selective chemical or combination of chemicals or drugs. The absorbent elements may be formed as a yarn and



provided with various properties including alternative rates of absorption or take-up of the chemical, as well as alternative rates of release or delivery of the chemical. This may be accomplished by blending various fibers within a single yarn element or by controlling the density of the weave or the chemical or mechanical treatment of the surface of the yarn element.

5           The releasing element may also be made of an absorbable material that releases the chemical or drug as the element desolves in body fluids. The agents may be time-released or bolused, depending on the properties of the fiber elements. The agents to be released or administered can be compounded so that a single woven or braided element contains a variety of agents to be delivered at defined rates and dosages over different times. Many other  
10 combinations of elements and materials will be apparent to provide the stent with selective characteristics desirable in a particular operative setting.

          Although exemplary embodiments of the invention have been shown and described, many other changes, modifications, and substitutions will now be apparent to those of ordinary skill in the art, without necessarily departing from the spirit and scope of this invention  
15 as set forth in the following claims.

CLAIMS

1. A stent, comprising:  
a stent body formed of fibers intermingled to form a mesh, the body having the general shape of a cylinder; and  
an enlarged-diameter retention member having the general shape of a cone with a base and an apex, the retention member being formed adjacent to the stent body and integral with the stent body.
2. The stent recited in Claim 1 wherein:  
the stent body has a proximal end and a distal end; and  
the apex of the cone forming the retention member faces distally of the stent body.
3. The stent as recited in Claim 1, further comprising:  
a rigid collar disposed at a distal end of the cone-shaped retention member, the rigid collar defining an aperture; and  
a compression sleeve adapted for fitting within the stent body, and for contacting the rigid collar around the aperture.
4. The stent as recited in Claim 3, the stent being configurable into an insertion configuration by application of a distally directed force applied through the rigid collar by the compression sleeve, and being configurable into an operative configuration by removal of the distal force from the rigid collar.
5. The stent as recited in Claim 4, further comprising a guidewire adapted for fitting within the stent body and through the aperture of the rigid collar.
6. The retention member as recited in Claim 1, wherein the stent body includes a plurality of convolutions.
7. The retention member as recited in Claim 6, wherein the plurality of convolutions include a particular convolution disposed generally intermediate the stent body.

8. The retention member as recited in Claim 7 wherein the plurality of convolutions cover a majority of the stent body.

9. A tube operable as a stent, the tube comprising:

a proximal tube end;

a distal tube end;

a lumen extending from the proximal tube end to the distal tube end; and

5 a collar disposed at the distal end, the collar being adapted for receiving a distal force from within the lumen, the tube being transformable from a short-length, large-diameter operable configuration to a long-length, small-diameter insertable configuration when the distal force is applied to the collar, and the tube being transformable back into the short-length, large-diameter operable configuration when the distal force is removed.

10 10. The tube as recited in Claim 9, the tube further comprising:

a wall formed of a braided material; and

a retention member formed in the wall of braided material, the retention member comprising a radially-increasing portion and a radially-decreasing portion.

11. The tube as recited in Claim 10, the radially-increasing portion extending substantially perpendicularly to a portion of the wall around a circumference of the wall; and the radially-decreasing portion comprising a cone shape having an axis parallel with an axis of the tube.

12. A stent, comprising:

a radially-contractible tube having a proximal tube end, a distal tube end, a diameter, and a lumen extending from the proximal tube end to the distal tube end; and

5 an actuator removably disposed within the lumen for increasing a distance between the proximal tube end and the distal tube end, to thereby reduce the diameter of the radially-contractible tube.

13. A method of accessing a body passage, comprising the following steps:  
converting a stent into a long-length, small-diameter insertion configuration by  
applying tension between a proximal end of the stent and a distal end of the stent, to thereby  
increase a distance between the proximal end of the stent and the distal end of the stent;  
5 inserting the stent into a body passage of a patient;  
moving the stent through the body passage of the patient to a desired location; and  
converting the stent into a small-length, large-diameter stent configuration by  
removing the tension to thereby decrease the distance between the proximal end of the stent and  
the distal end of the stent.

14. A method of making a stent, which is transformable between a large-  
diameter configuration and a small-diameter configuration, the stent being transformable from  
the large-diameter configuration to the small-diameter configuration upon application from a  
compression sleeve of a distal force onto a distal end of the stent, the method comprising the  
5 following steps:

providing a woven tubular structure;  
placing the woven tubular structure over a forming tool, the forming tool  
comprising a cylindrical body having a first diameter corresponding to the large-diameter  
configuration, and having a second diameter that is smaller than a diameter of the compression  
10 sleeve;

irradiating the woven tubular structure with thermal energy, to thereby set a  
portion of the woven tubular structure at the first diameter and to set a distal end of the woven  
tubular structure at the second diameter; and

removing a resulting structure from the forming tool.

15. The method as recited in Claim 14, the forming tool comprising a cone-  
shaped portion near a distal end of the cylindrical body; and

the second diameter corresponding to a diameter of a guidewire.

16. The method as recited in Claim 14, the irradiating step being preceded by  
a step of folding a portion of the woven tubular structure, located proximally of the cone-shaped  
portion, proximally upon the cylindrical body to thereby form a retention member.

17. The method as recited in Claim 14, the forming tool comprising a cylindrical mandrel with both a first cone-shaped portion near a distal end of the cylindrical mandrel and a second cone-shaped portion near a proximal end of the cylindrical mandrel, and the irradiating step being preceded by the following steps:

- 5           folding a portion of the woven tubular structure, located proximally of the first cone-shaped portion, proximally upon the mandrel to thereby form a first retention member; and
- folding a portion of the woven tubular structure, located distally of the second cone-shaped portion, distally upon the mandrel to thereby form a second retention member.

18. The method as recited in Claim 17, the removing step being followed by a step of cutting the resulting structure in half, to thereby bisect the resulting structure into two stents.

19. A method of iteratively increasing a diameter of a lumen of a body passage, comprising the following steps:

- inserting a stent into a body passage of a patient;
- moving the stent through the body passage of the patient to a desired location; and
- 5           iteratively increasing a diameter of the stent, a first iterative increase of the diameter of the stent resulting in the diameter of the lumen increasing to a first enlarged diameter, and a second iterative increase of the diameter of the stent resulting in the diameter of the lumen increasing to a second enlarged diameter which is greater than the first enlarged diameter.

20. The method as recited in Claim 19, the inserting step being preceded by a step of converting the stent into a long-length, small-diameter insertion configuration by increasing a distance between a proximal end of the stent and a distal end of the stent.

21. The method as recited in Claim 20, the step of iteratively increasing a diameter of the stent, including a step of converting the stent into a small-length, large-diameter stent configuration by decreasing a distance between a proximal end of the stent and a distal end of the stent.

22. A stent adapted to be releasably placed in a body conduit to increase the patency of the body conduit, comprising:

a stent body having an axis extending between a proximal end and a distal end, the stent body having a first diameter;

5 a retention member integral with the stent body and having a second diameter in a relaxed state and a third diameter in a tensioned state; and

the third diameter being greater than the first diameter and less than the second diameter.

23. The stent recited in Claim 22 wherein the retention member is a first retention member and the stent further comprises:

a second retention member disposed at the proximal end of the stent body.

24. The stent recited in Claim 22 wherein the retention member further comprises:

portions extending radially inwardly with progressive distal positions along the axis of the stent.

25. The stent recited in Claim 24, wherein:

the portions are first portions; and

the retention member further comprises second portions disposed proximal of the first portions and defining a maximum diameter of the retention member.

26. The stent recited in Claim 24 wherein the retention member further comprises:

third portions disposed proximal of the second portions and tapering radially inwardly with progressive proximal positions along the axis.

5

27. The stent recited in Claim 26 wherein the third portions have a first angle with the axis in the tension state, and a second angle with the axis greater than the first angle in the relaxed state.

28. The stent recited in Claim 27 wherein the third portions are generally perpendicularly axis in the relaxed state.

29. The stent recited in Claim 24 wherein the portions of the retention member are configured in the shape of a cone having a base and an apex.

30. The stent recited in Claim 29 wherein the first portions define a hole at the apex of the cone.

31. The stent recited in Claim 26, wherein:  
the first portions and the third portions are separated by a particular distance; and  
the diameter of the second portions increases as the particular distance decreases.

32. A stent assembly for increasing the patency of a body conduit, comprising:  
a stent having a lumen extending between a proximal end and a distal end, the lumen having a first diameter;  
a retention member having a second diameter larger than the first diameter;  
5 an activation device removably positioned in the lumen of the stent and adapted to be compressed to tension the proximal end of the stent relative to the distal end of the stent in order to place the stent in a low-profile state; and  
the actuation device being removable from the lumen of the stent to place the stent in a high-profile state within the body conduit.

10

33. The stent assembly recited in Claim 32 wherein the retention member has portions tapering radially inwardly distally from the second diameter to a third diameter less than the first diameter of the stent body.

34. The stent assembly recited in Claim 33 wherein a retention member defines an axial hole having a third diameter.

35. The stent assembly recited in Claim 32, further comprising:  
a guidewire adapted to be removably disposed through the lumen of the stent and the hole of the retention member.
36. The stent assembly recited in Claim 32 wherein the stent body includes a plurality of corrugations.
37. The stent assembly recited in Claim 32 wherein the retention member is a first retention member, and the stent further comprises a second retention member disposed at the proximal end of the stent.
38. The stent assembly recited in Claim 32 wherein the stent includes a plurality of fibers intermingled to form a tubular mesh.
39. The stent assembly recited in Claim 38 wherein the fibers are formed of a thermo-plastic material.
40. The stent assembly recited in Claim 32 wherein the stent further comprises an elastomeric material disposed on an outer surface of the stent.
41. The stent assembly recited in Claim 32, further comprising:  
a tether attached to the stent and adapted to facilitate removal of the stent from the body conduit.
42. The stent assembly recited in Claim 34 wherein the retention member further comprises a rigid collar disposed around the hole of the third portions.
43. A stent adapted for use in a body conduit to facilitate a flow of fluid through the conduit, the stent having an axis extending between a proximal end and a distal end, and comprising:



a plurality of filaments disposed relative to each other generally along the axis of  
5 the stent, the filaments providing the stent with an outer surface which is generally cylindrical in  
configuration; and

a material disposed relative to the filaments and having properties for maintaining  
the filaments of the stent in a predetermined orientation at least during insertion of the stent into  
the body conduit.

44. The stent recited in Claim 43 wherein the material is impregnated into  
the filaments.

45. The stent recited in Claim 43 wherein the material forms a coating on  
the filaments.

46. The stent recited in Claim 45 wherein the coating is disposed on the outer  
surface of the stent.

47. The stent recited in Claim 43 wherein the material provides the stent with  
a column strength sufficient to permit the stent to be pushed without guiding structure during the  
insertion of the stent into the body conduit.

48. The stent recited in Claim 43, wherein:  
the filaments have generally rigid properties in the presence of the material and  
generally flexible properties in the absence of the material;  
the material has characteristics for being at least partially removed from the  
5 filaments when present in the body conduit; whereby

the stent is generally rigid when the material is sufficiently present prior to  
insertion, and generally flexible when the material is removed from the filaments after insertion  
of the stent into the body conduit.

49. The stent recited in Claim 43, wherein:  
the filaments have properties for providing the stent with a low-profile state and a  
high-profile state;

the material has characteristics for being at least partially removed from the  
5 filaments when present in the body conduit; whereby

the stent has a generally low profile when the material is present prior to insertion,  
and a generally high profile when the material is at least partially removed from the filaments  
after insertion of the stent into the body conduit.

50. The stent recited in Claim 49 wherein the material is bio-absorbable.

51. The stent recited in Claim 50 wherein the bio-absorbable material includes  
polyglycolic acid.

52. The stent recited in Claim 43 wherein the filaments are woven.

53. The stent recited in Claim 43 wherein the filaments are braided.

54. The stent recited in Claim 43 wherein the filaments are twisted  
about the axis.

55. The stent recited in Claim 43 wherein the filaments extend between the  
proximal end and the distal end in a generally parallel relationship.

56. The stent recited in Claim 43 wherein the filaments facilitate a wicking of  
the fluid between the proximal end and the distal end of the stent.

57. The stent recited in Claim 43 wherein the filaments include:  
a first filament formed of a first material; and  
a second filament formed of a second material different than the first material.

58. A stent adapted to be inserted into a body conduit, including:  
a stent body having first characteristics and second characteristics, the first  
characteristics of the body being advantageous during insertion of the stent into the body cavity,

and the second characteristics being advantageous when the stent is operatively disposed in the  
5 body conduit; and

a material disposed relative to the body and having first properties and second properties, the first properties of the material facilitating the first characteristics of the stent body during insertion, and the second properties of the material facilitating the second characteristics of the stent body when operatively disposed.

59. The stent recited in Claim 57 wherein the first properties of the material inhibit the second characteristics of the stent body during insertion of the stent into the body conduit.

60. The stent recited in Claim 57 wherein the stent body is formed of a multiplicity of filaments.

61. The stent recited in Claim 58 wherein the material is at least one of impregnated into the filaments and coated on the filaments.

62. A stent having an elongate configuration defined by a proximal end and a distal end, the stent being adapted for insertion into a body conduit to increase the patency of the body conduit, the stent comprising:

at least one element extending between the proximal end and the distal end of the  
5 stent, the element having a relatively high tensile strength sufficient to inhibit breakage during insertion and removal of the stent relative to the body passage; and

the at least one element forming sections movable relative to each other to provide the stent with a relatively soft configuration when operatively disposed in the body conduit.

63. The stent recited in Claim 61 wherein the element forms a spring having convolutions, and the sections of the element comprise the convolutions of the spring.

64. The stent recited in Claim 61 wherein the element is a first element and the stent further comprises:

a second element movable relative to the first element between the first end and a second end of the stent.

65. The stent recited in Claim 63 wherein the first and second elements are woven.

66. The stent recited in Claim 63 wherein at least one of the elements is bio-absorbable.

67. The stent recited in Claim 63 wherein at least one of the elements is absorbent.

68. A stent adapted for use in a body conduit to facilitate a flow of fluid through the conduit, the stent having an axis extending between a proximal end and a distal end, and comprising:

a first element extending generally longitudinally between the proximal end and  
5 the distal end of the stent;

the first element having absorption characteristics; and

a first absorbent having medical characteristics and being absorbed into the first element, the first absorbent providing the stent with properties dependent on the medical characteristics of the absorbent.

69. The stent recited in Claim 68 wherein the absorption characteristics of the first element are first absorption characteristics, the stent further comprising:

a second element extending generally between the proximal end and the distal end of the stent;

5 the second element having second absorption characteristics different than the first absorption characteristics of the first element.

70. The stent recited in Claim 68, further comprising:  
a second element extending generally between the proximal end and the distal end of the stent in a movable relationship with the first element.

71. The stent recited in Claim 68 wherein the first absorbent includes at least one of an antibiotic, an anesthetic, an analgesic, a material to control encrustation, and a radiopaque material.

72. The stent recited in Claim 69 wherein the first element is formed of a first material and the second element is formed of a second material different than the first material.

73. The stent recited in Claim 69, wherein:  
the first element has first absorption characteristics; and  
the second element has second absorption characteristics different than the first absorption characteristics of the first element.

74. The stent recited in Claim 73, wherein:  
the first absorption characteristics of the first element provide for leaching of the first absorbent at a first rate; and  
the second absorption characteristics of the second element provide for leaching  
5 of the second absorbent at a second rate.

75. The stent recited in Claim 74 wherein the first absorbent is different than the second absorbent.

76. The stent recited in Claim 72, wherein:  
at least one of the proximal tube end and the distal tube end of the radially-contractible tube is formed with the natural configuration of a coil.

77. The stent recited in Claim 72 further comprising:  
a radiopaque material disposed relative to the radially-contractible tube.

78. A body portion having the configuration of a tube with a lumen extending between a proximal end and a distal end;

an anchor portion coupled to the body portion at the distal end of the body portion, the anchor portion having a hollow configuration and being in fluid communication with the lumen of the body portion; and

at least one of the body portion and the anchor portion being formed of a mesh.

79. The ureteral stent recited in Claim 78 wherein the anchor portion has a tubular configuration with a first end and a second end, the first end being coupled to the distal end of the body portion.

80. The ureteral stent recited in Claim 79 wherein the anchor portion has properties for being heatset to the configuration of a pigtail.

81. The ureteral stent recited in Claim 80 wherein the anchor portion is formed of the mesh.

82. The ureteral stent recited in Claim 81 wherein the body portion is formed of the mesh and is integral with the mesh of the anchor portion.

83. The ureteral stent recited in Claim 78, wherein:  
the tubular configuration of the anchor portion has a first diameter; and  
the body portion is heatset to a second diameter greater than the first diameter.

84. The ureteral stent recited in Claim 78 wherein the anchor portion has a first anchor portion and the stent further comprises:

a second anchor portion coupled to the proximal end of the body portion.

85. The ureteral stent recited in Claim 79 wherein the first anchor portion includes a constriction.

86. The ureteral stent recited in Claim 78 wherein the anchor portion has a generally spherical configuration.

87. The ureteral stent recited in Claim 78, further comprising:  
a tether coupled to the proximal end of the body portion; and  
at least one of the body portion, anchor portion, and tether being formed of  
the mesh.

88. A method for introducing a stent into a ureter of a patient, comprising  
the steps of:

providing the stent with a woven mesh, tubular configuration, and a lumen  
extending between a proximal end and a distal end, the stent having a low-profile state and a

5 high-profile state;

inserting a positioner into the lumen of the stent;

longitudinally stretching the stent on the positioner to provide the stent with the  
low-profile state;

moving the positioner and the stent in the low-profile state into the ureter of the  
10 patient; and

removing the positioner from the lumen of the stent to change the configuration of  
the stent to the high-profile state.

89. The method recited in Claim 88 wherein the inserting step includes  
the steps of:

positioning a guidewire in the urethra of the patient;

moving the positioner and the stent over the guidewire; and

5 removing the guidewire from the stent, leaving the stent in the high-profile state.

90. The method recited in Claim 88 further comprising the steps of:

moving the stent in the low-profile state into an oversheath to provide the stent  
with a smooth outer surface during the moving step; and

removing the oversheath from the stent leaving the stent operatively disposed in  
5 the urethra of the patient.

91. The method recited in Claim 88, wherein:

the providing step includes the step of providing the distal end of the stent with a constriction; and

the inserting step includes the step of abutting the constriction of the stent with the  
5 positioner.

92. The method recited in Claim 88 wherein the providing step includes the step of heatsetting the stent in a configuration including a body portion and at least one anchor portion coupled to the body portion and having a coil configuration.

93. A stent system for facilitating the flow characteristics of a ureter of a patient, comprising:

a stent having a proximal end and a distal end;

a body portion of the stent having a first end and a second end in the configuration  
5 of a tube with a first diameter;

an anchor portion of the stent coupled to the first end of the body portion and having a second diameter less in the first diameter of the anchor portion, the anchor portion being provided with a constriction at the distal end of the stent;

a first positioner having a third diameter less than the second diameter of the  
10 anchor portion and greater than the diameter of the constriction of the anchor portion, the first positioner being adapted for removable disposition within the body portion and the anchor portion of the stent to an operative position in an abutting relationship with the constriction;

a third portion of the stent coupled to the second end of the body portion and having a third diameter less than the first diameter of the body portion; and

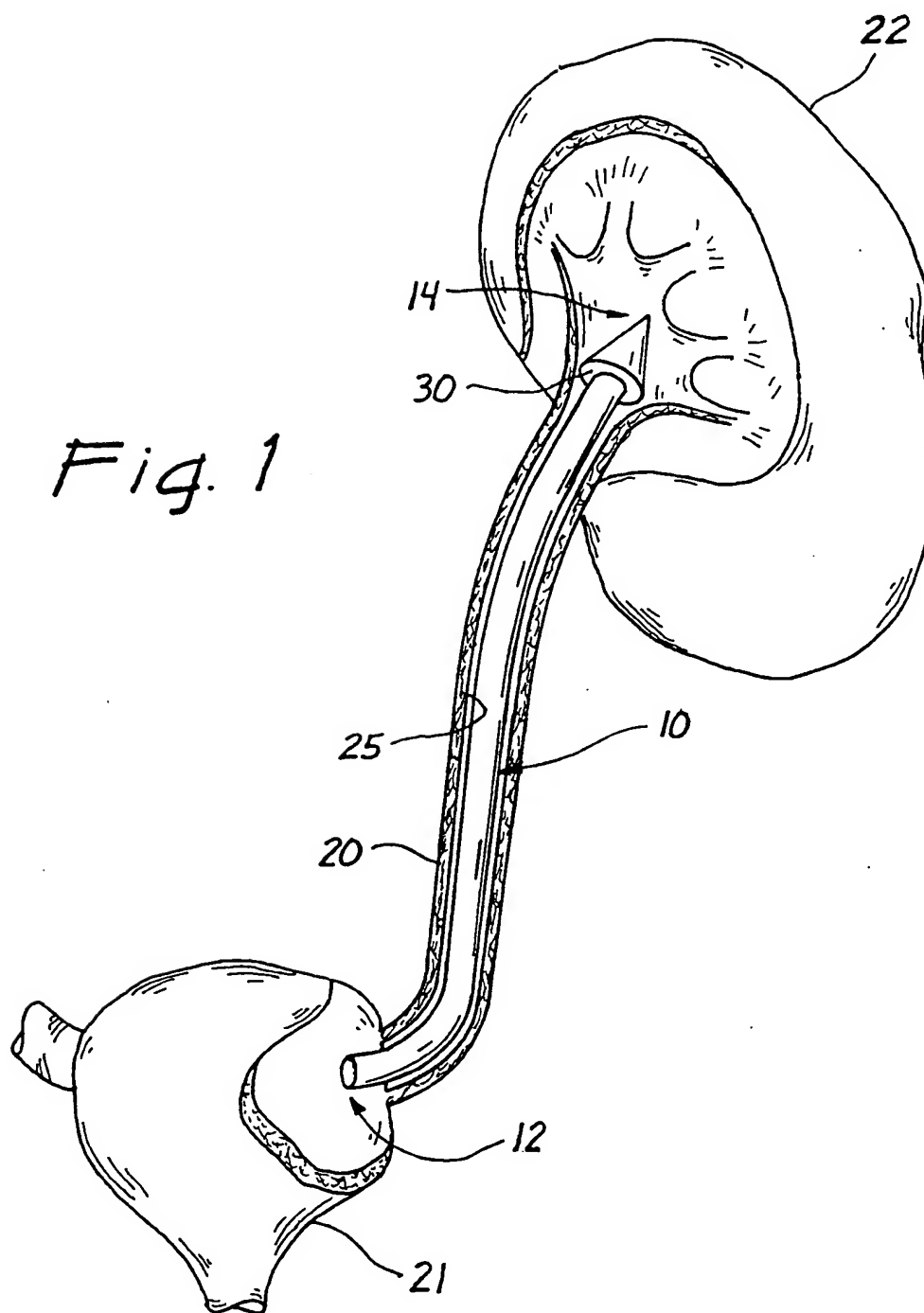
15 a second positioner having a fourth diameter less than at least one of the third diameter of the third portion and the first diameter of the body portion, the second positioner having properties facilitating removal of the first positioner from the anchor portion at the distal end of the stent.



94. The stent system recited in Claim 93, further comprising:  
an oversheath having a fourth diameter greater than the first diameter of the body portion to provide the stent with a smooth outer surface during insertion of the stent into the urethra.

95. The stent system recited in Claim 93, further comprising:  
a guidewire adapted for disposition in the urethra, the guidewire having properties for guiding the stent to an operative position in the ureter.

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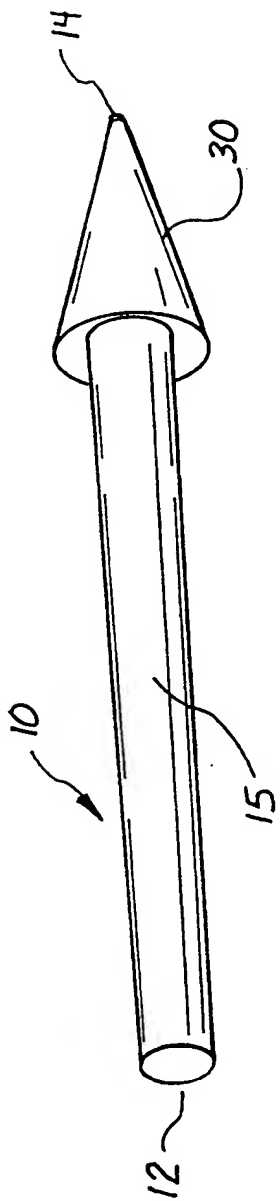


Fig. 2

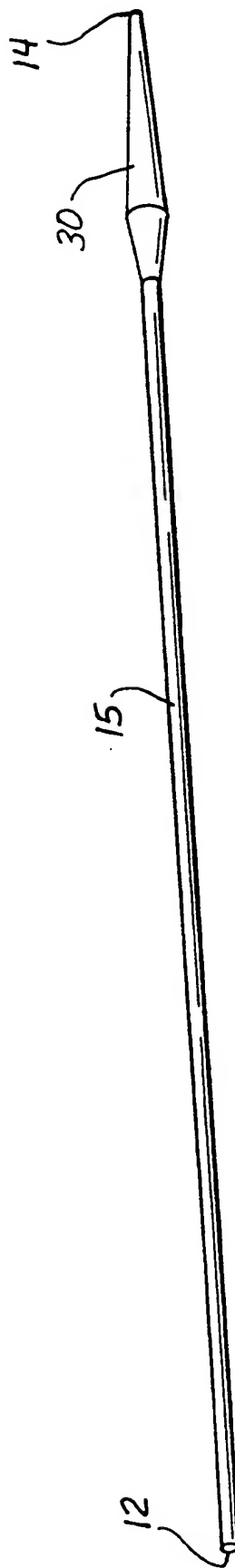


Fig. 3

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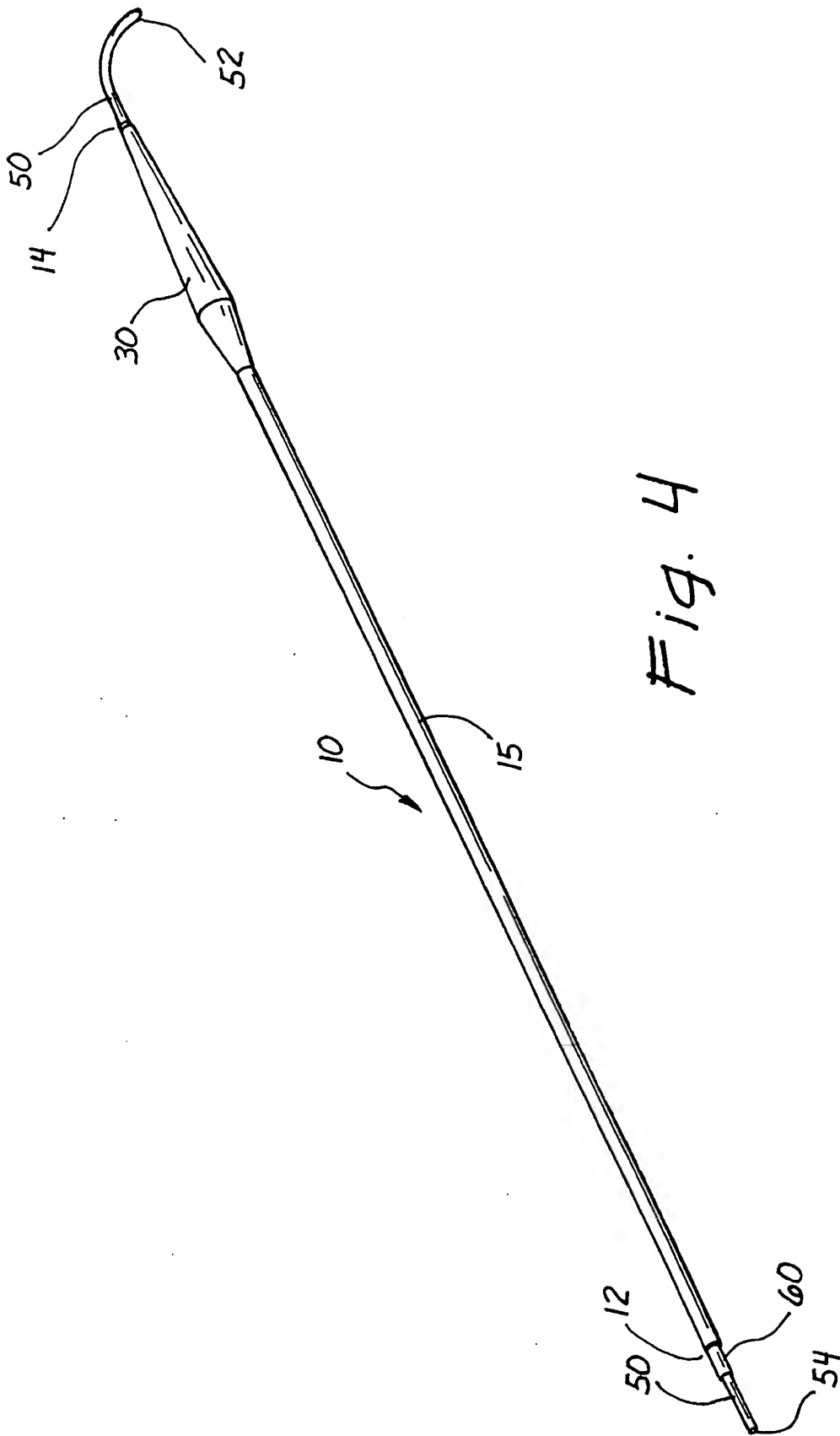
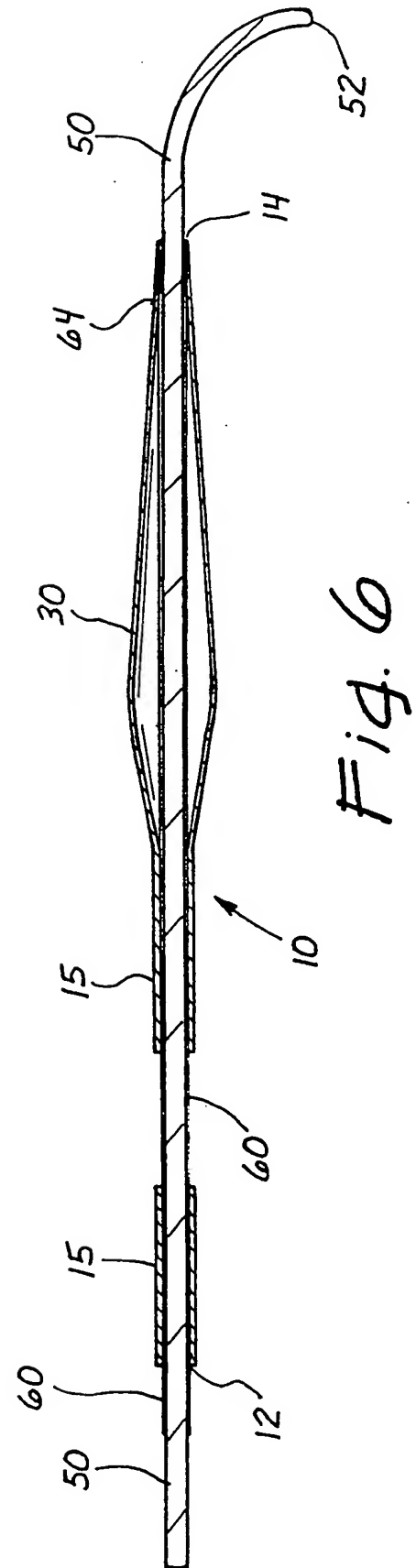
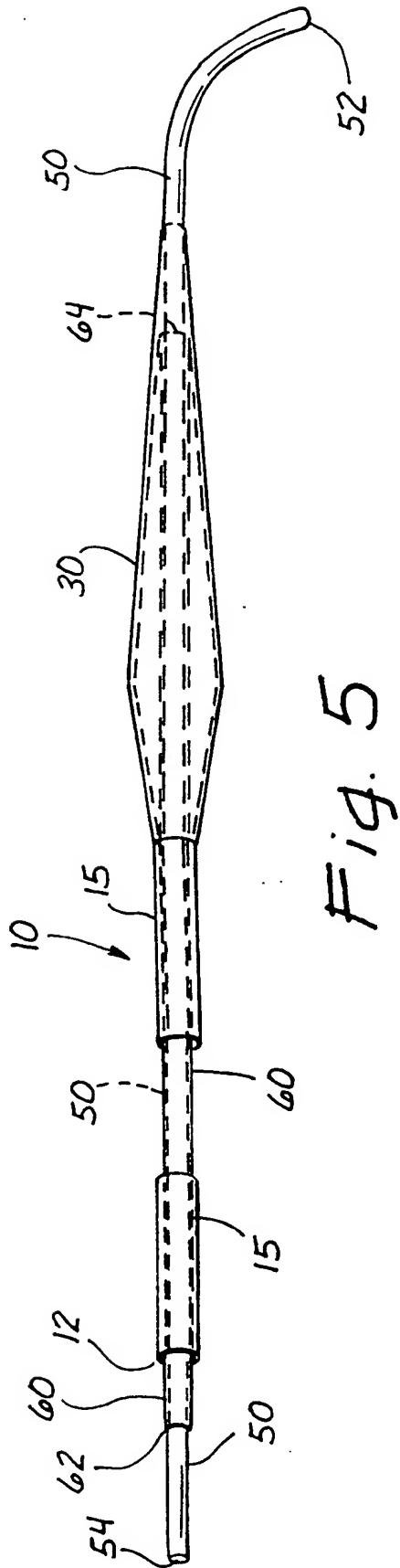


Fig. 4

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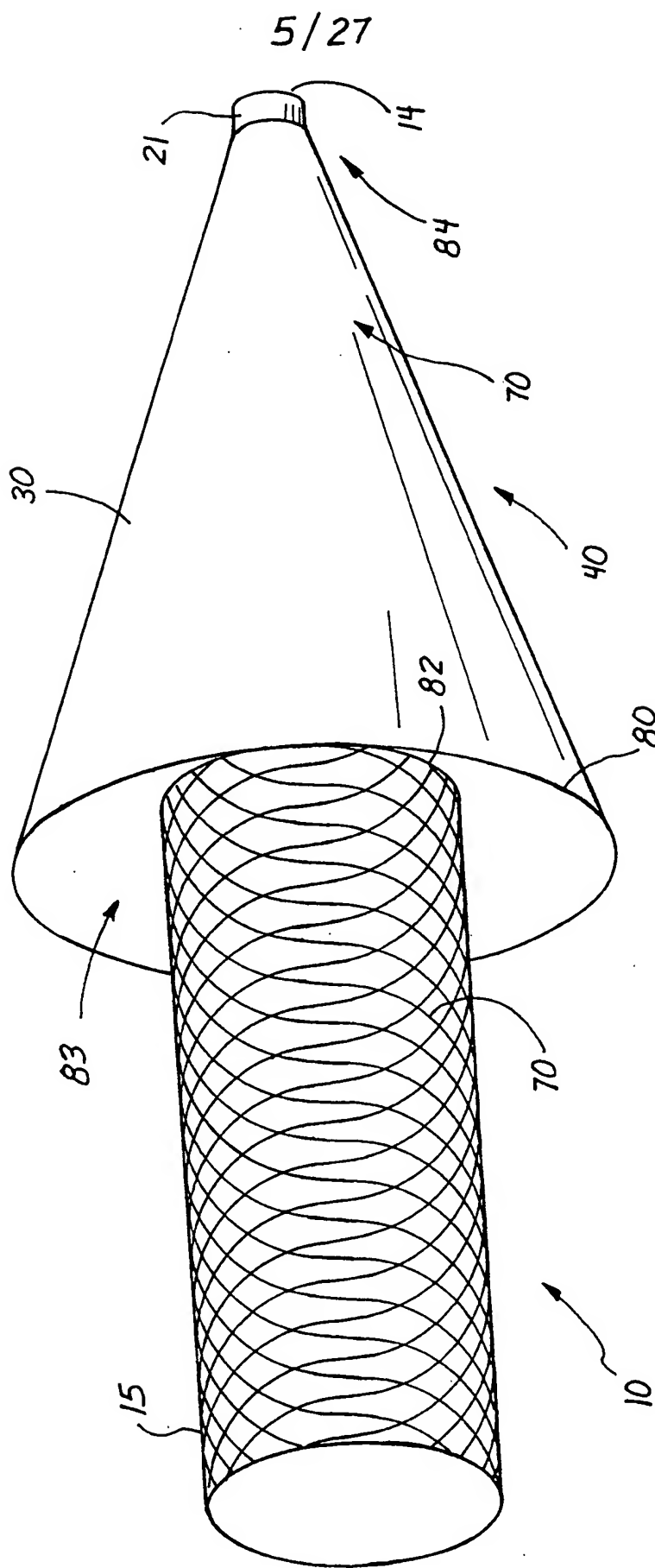
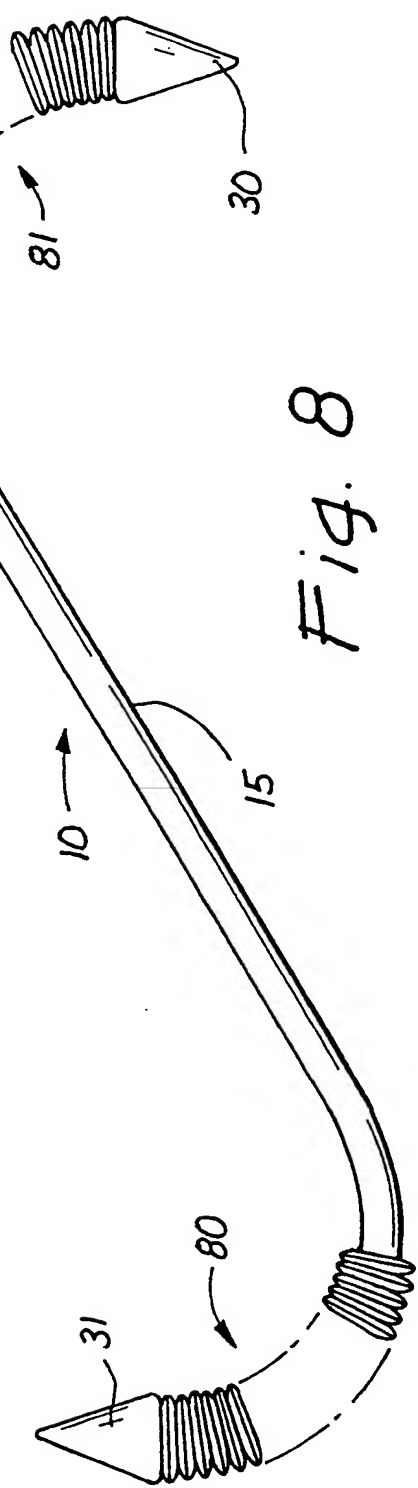
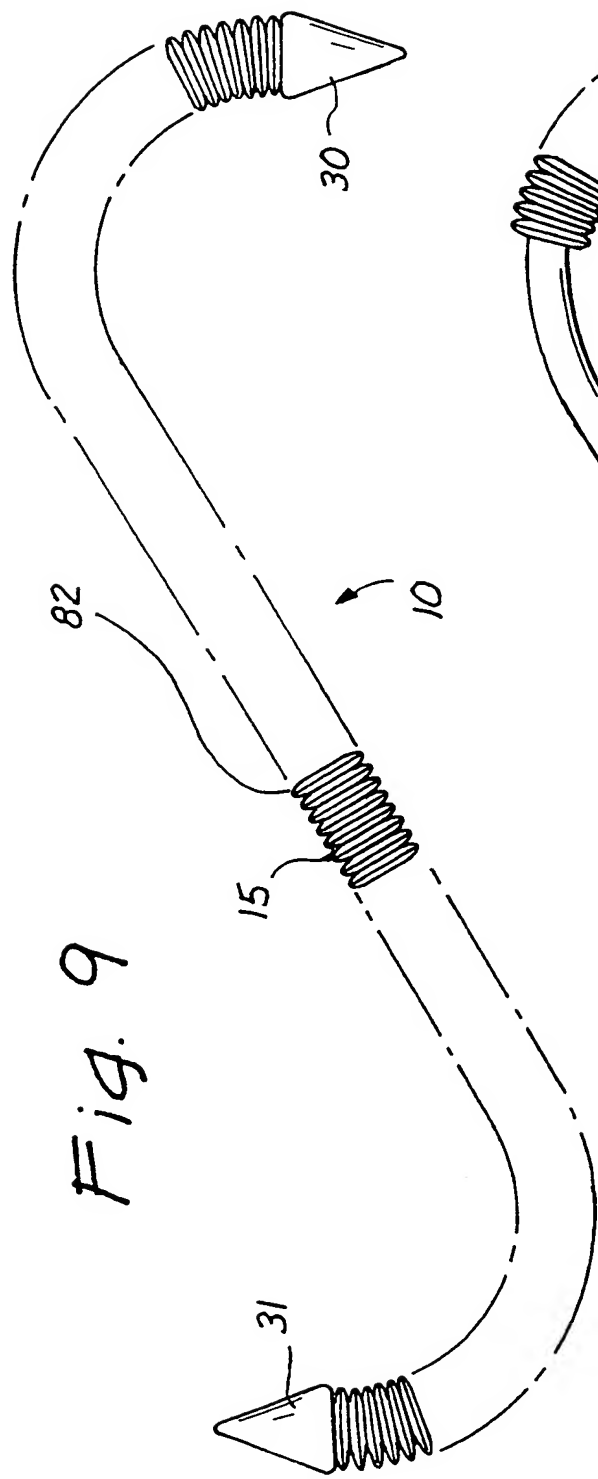
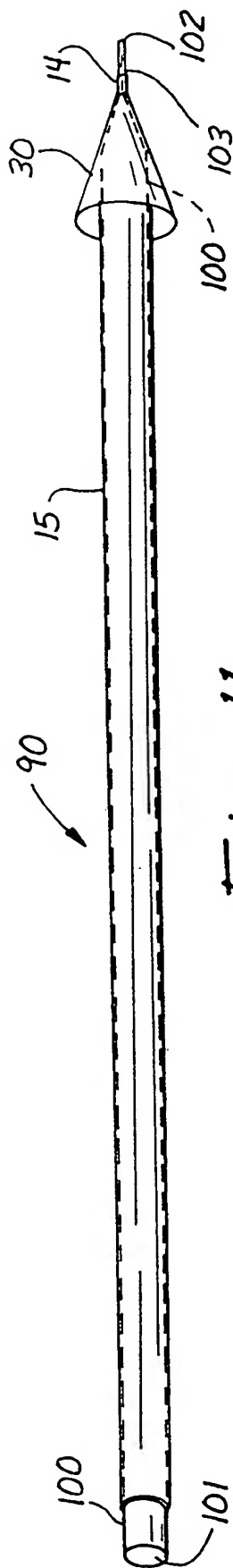
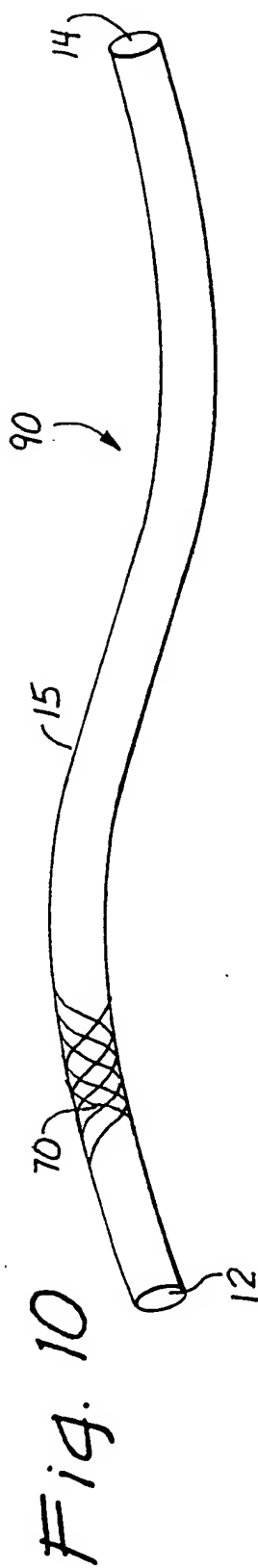


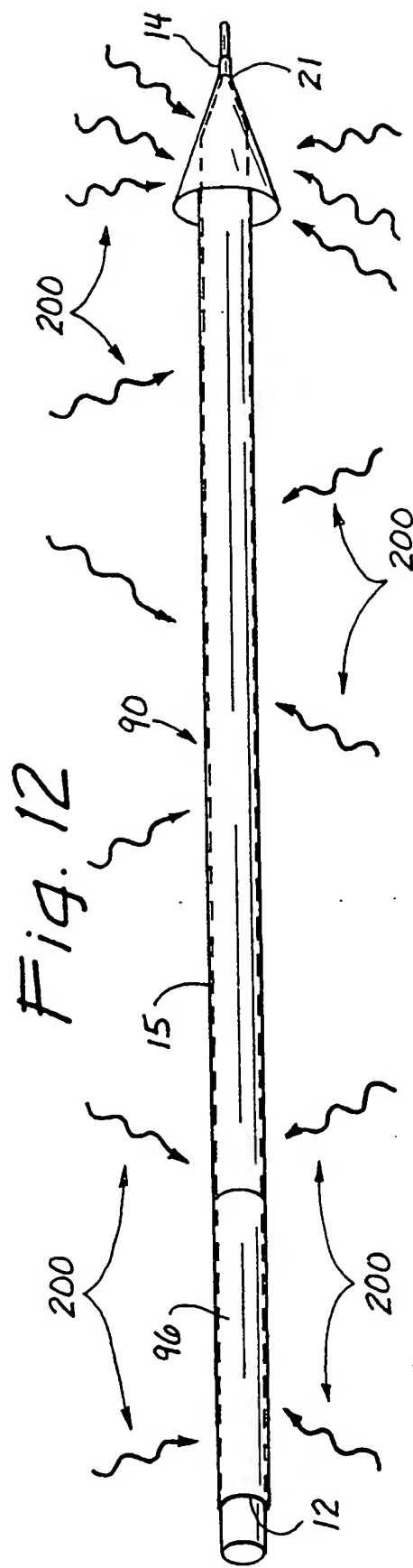
Fig. 7



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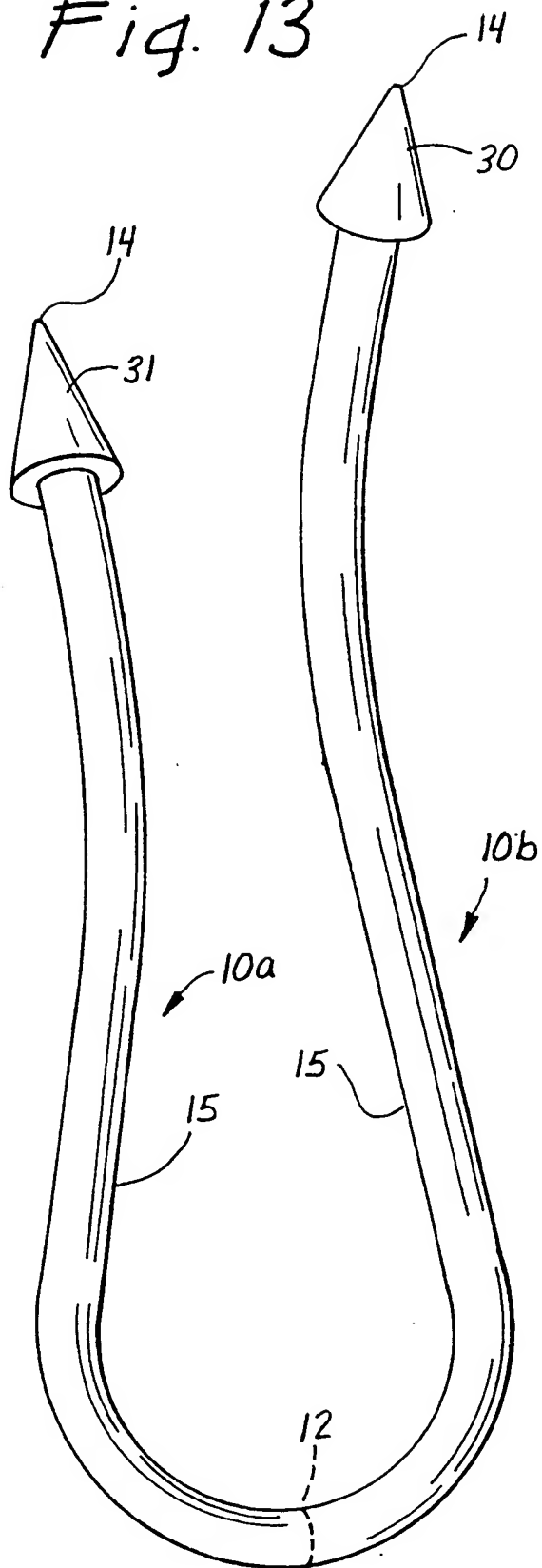
**Fig. 11**



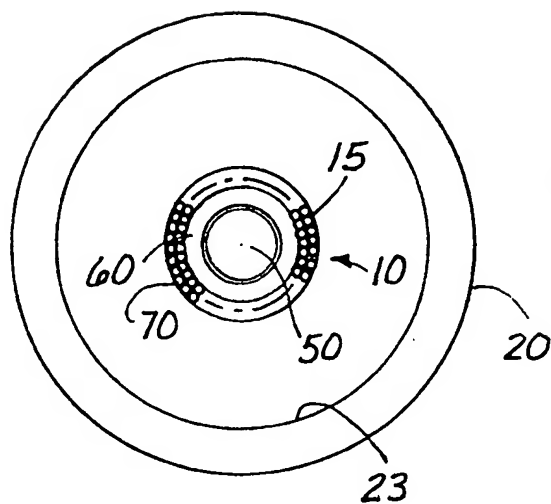
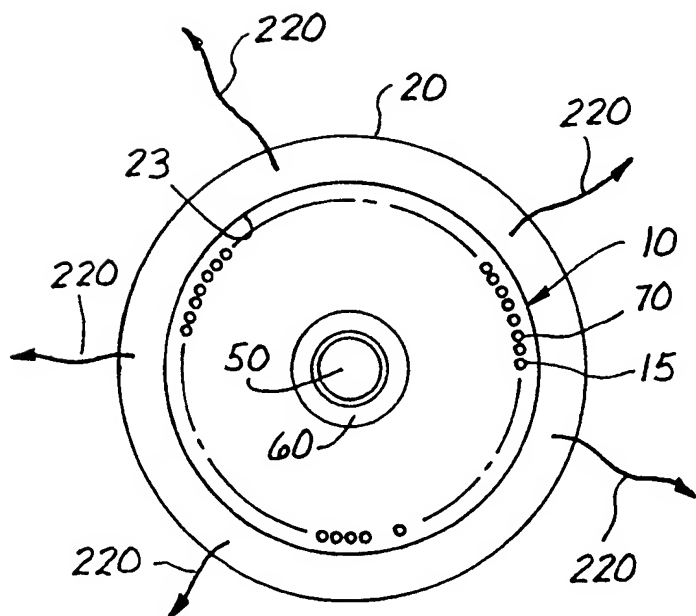
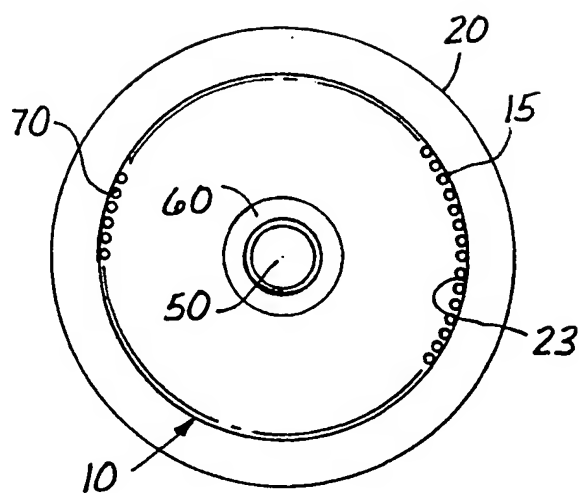


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Fig. 13



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*Fig. 15**Fig. 16**Fig. 17*

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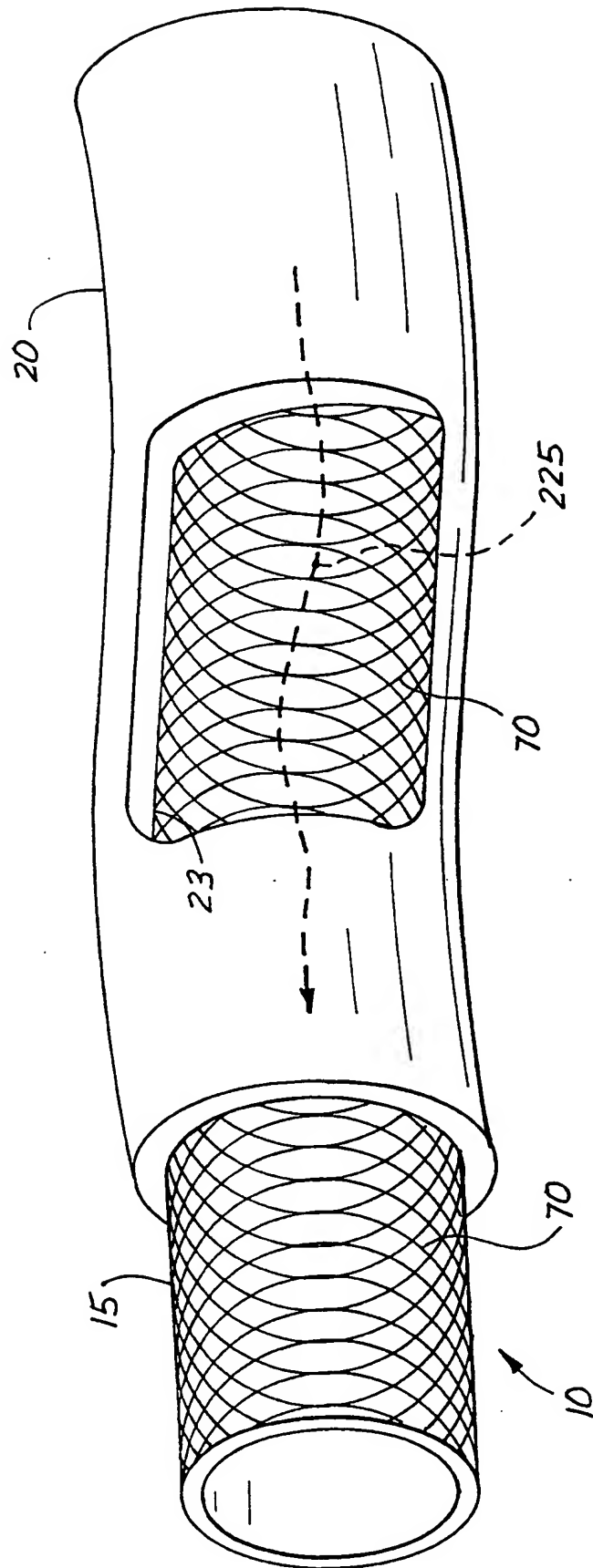


Fig. 18

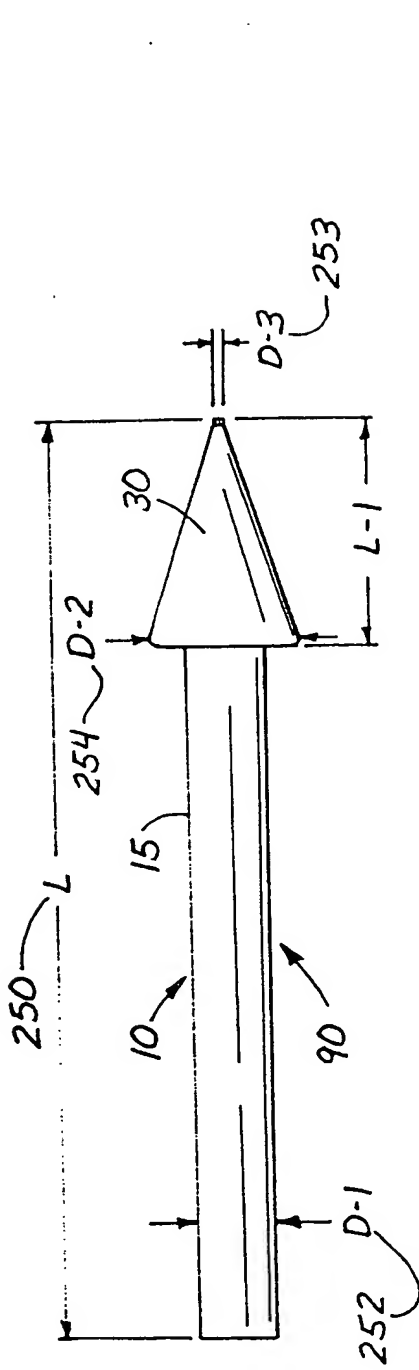


Fig. 19

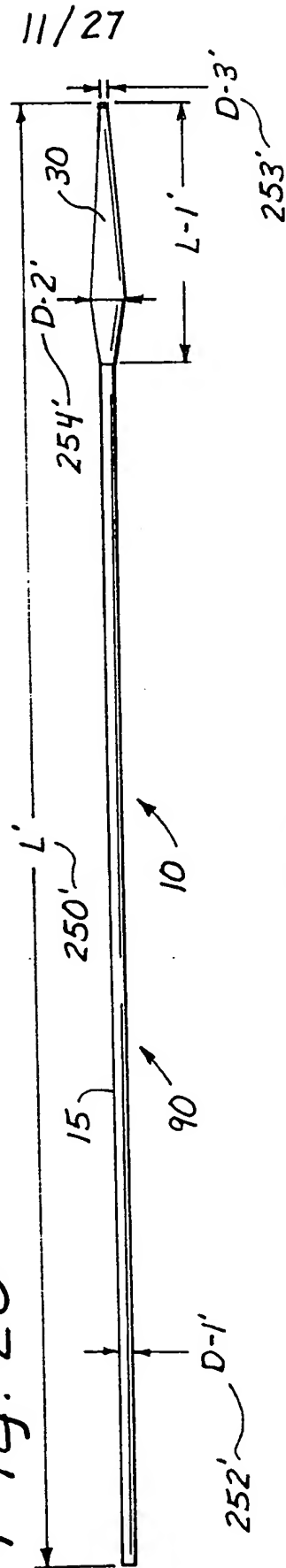


Fig. 20

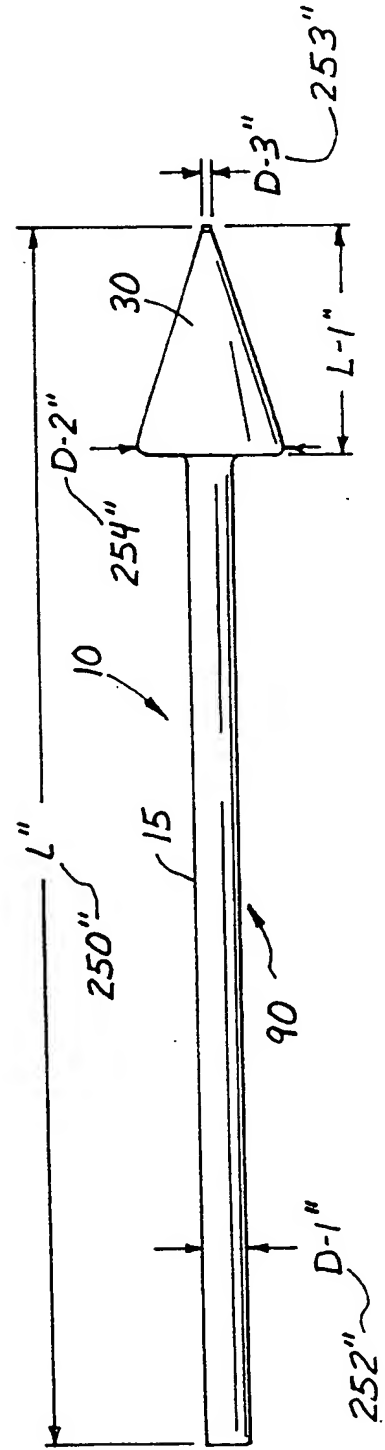


Fig. 21

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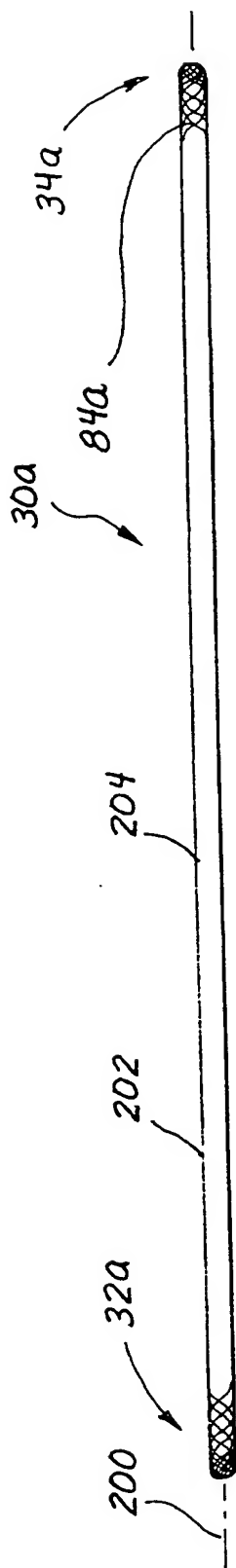


Fig. 22

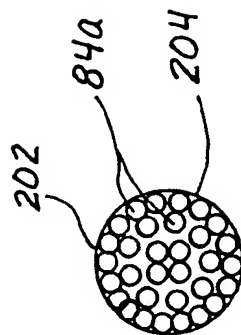


Fig. 24

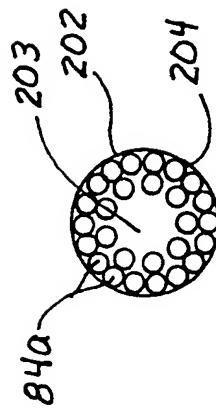


Fig. 23

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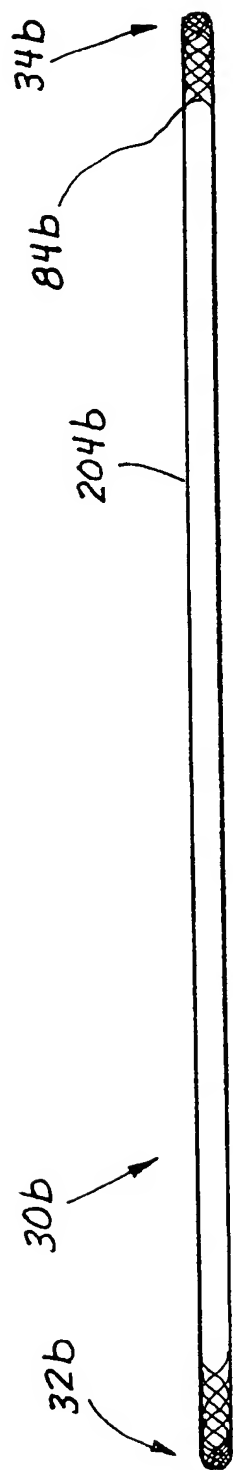


Fig. 25

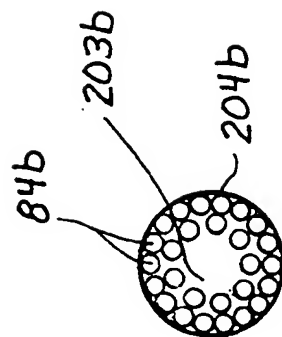


Fig. 26

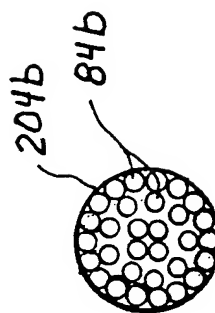
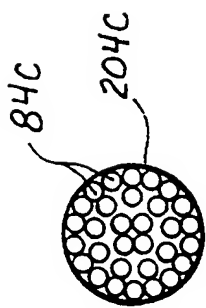
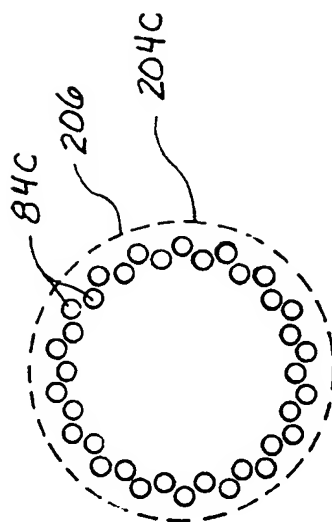
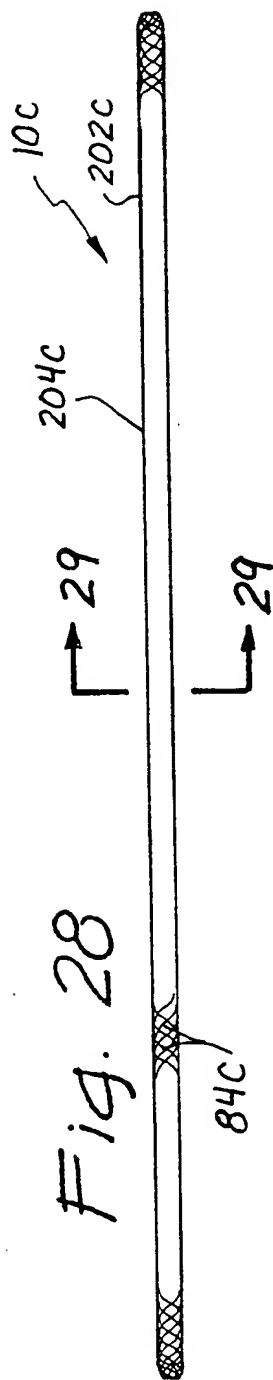


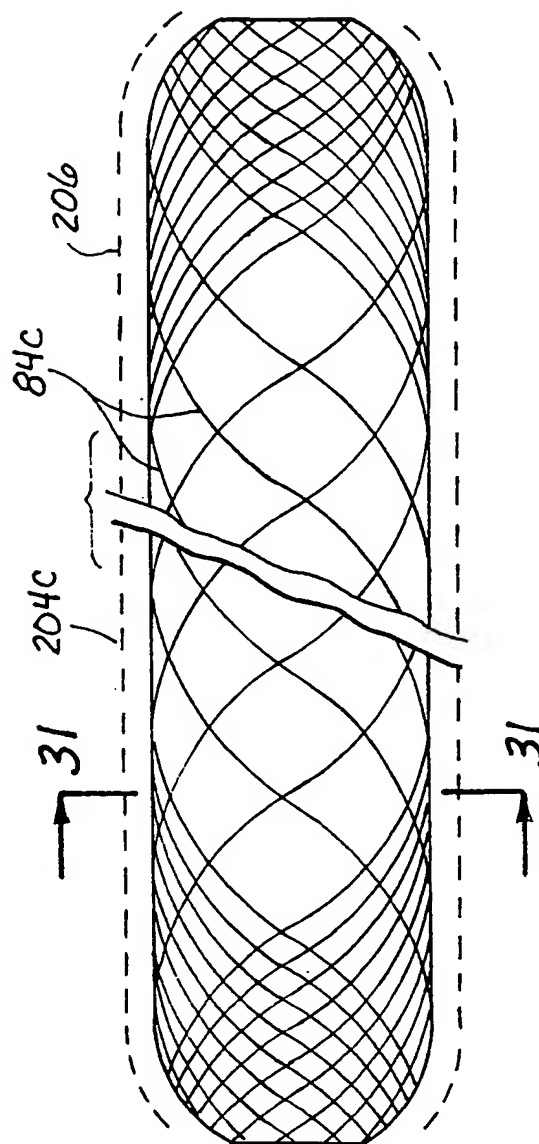
Fig. 27

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*Fig. 31*

*Fig. 29*



*Fig. 30*

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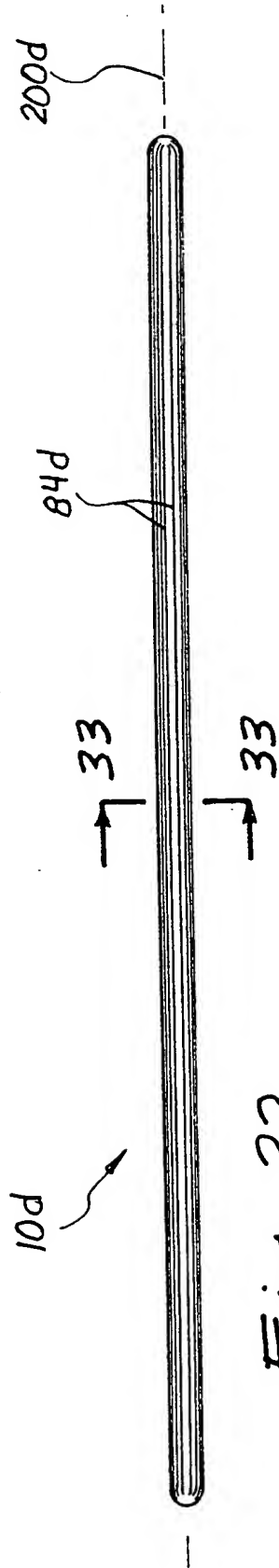


Fig. 32

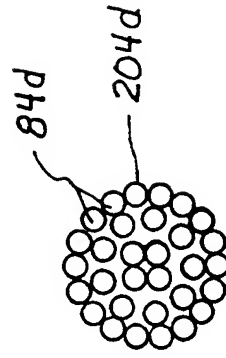


Fig. 34

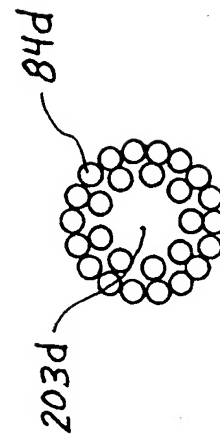


Fig. 33



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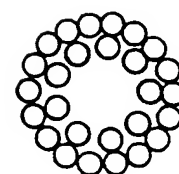
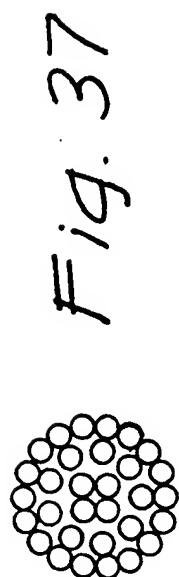
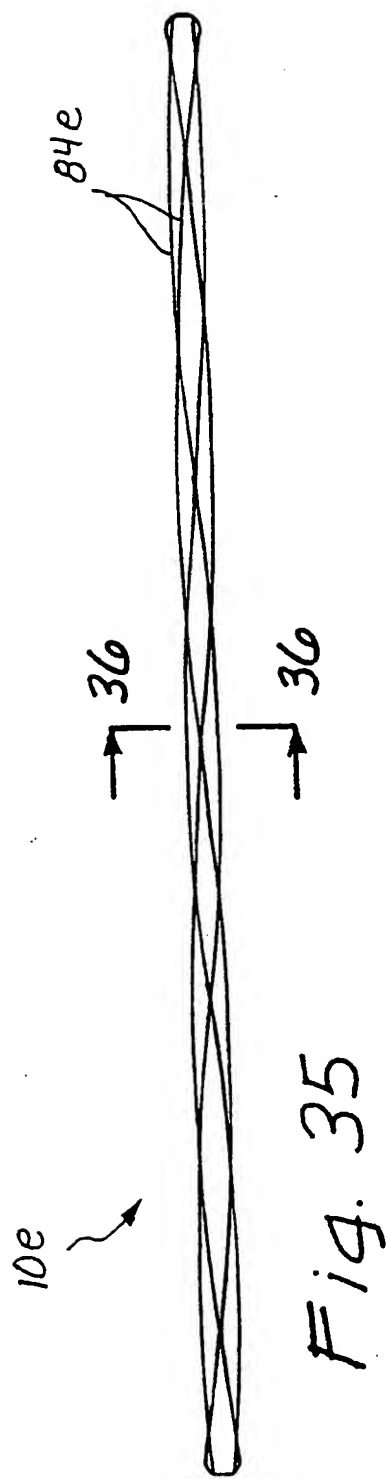
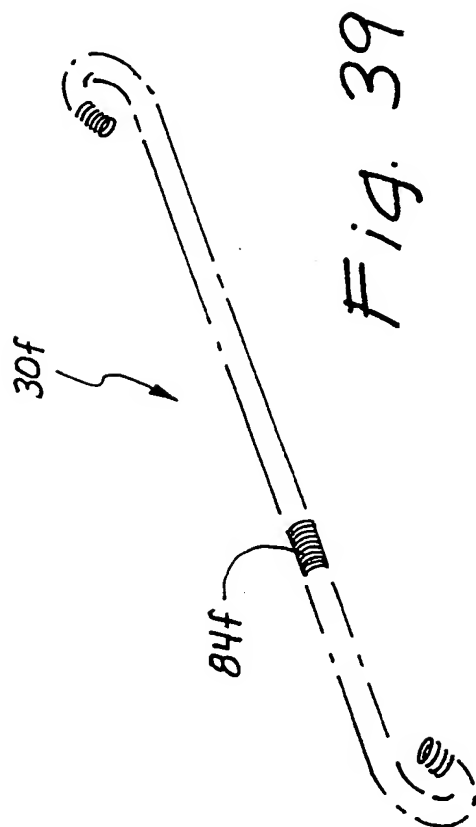
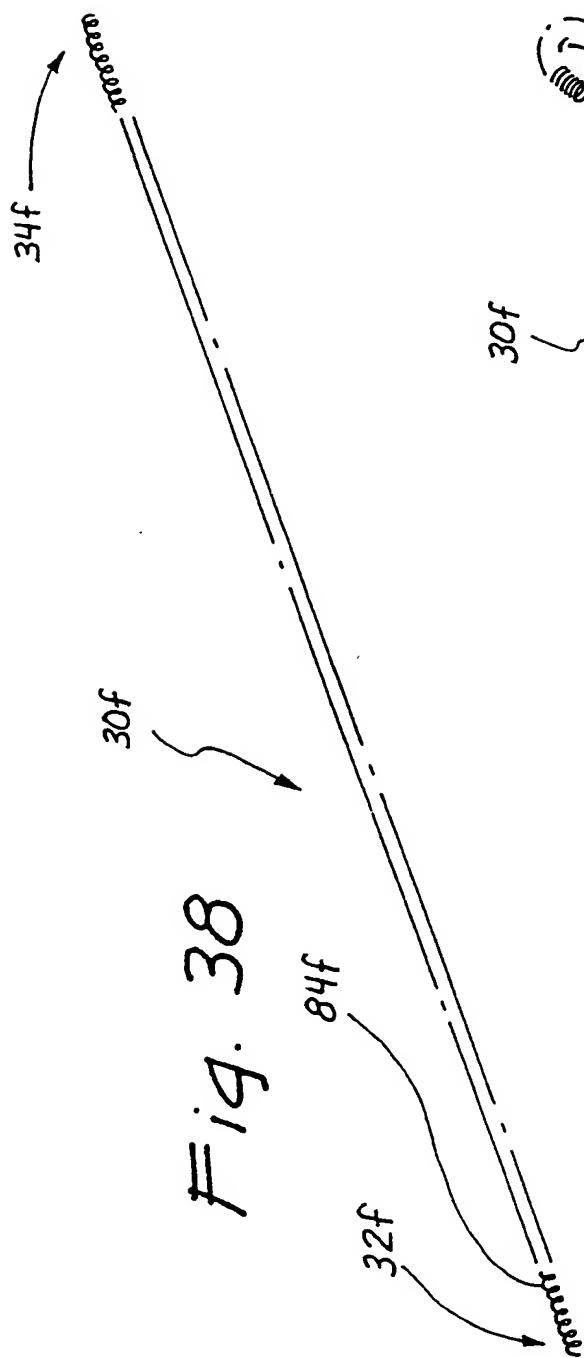


Fig. 36

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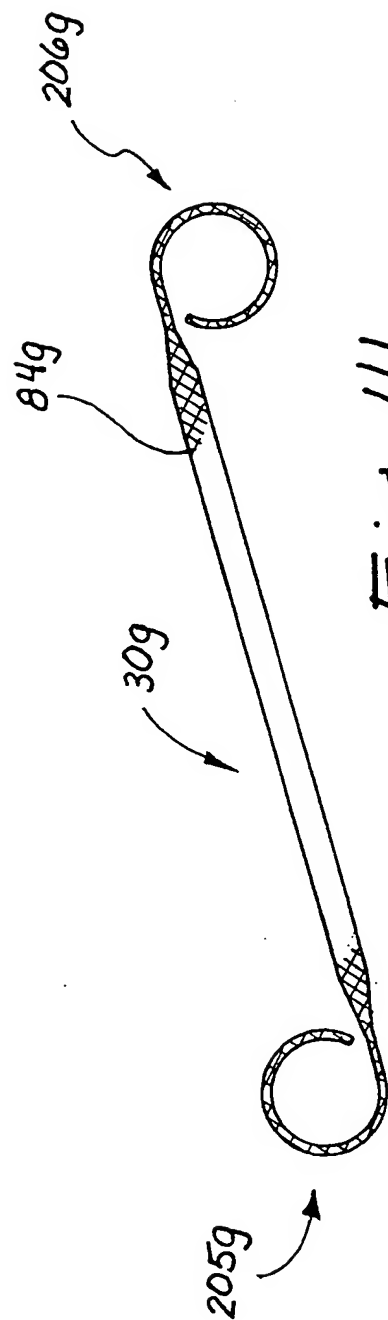
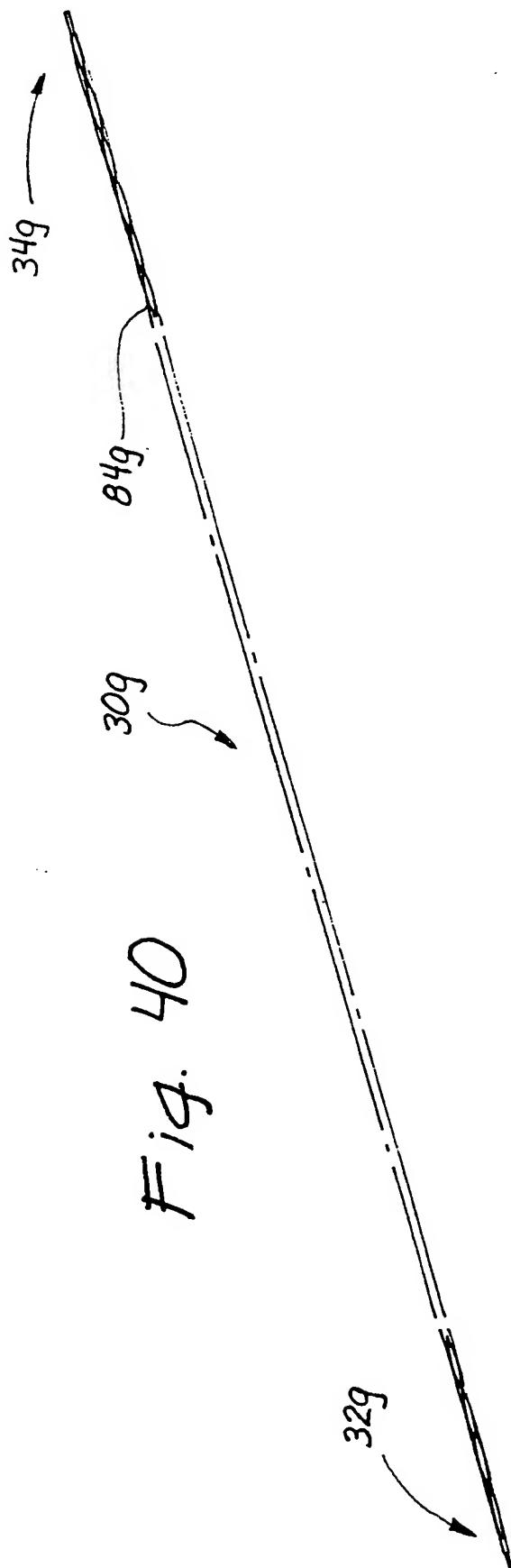


Fig. 41

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Fig. 43

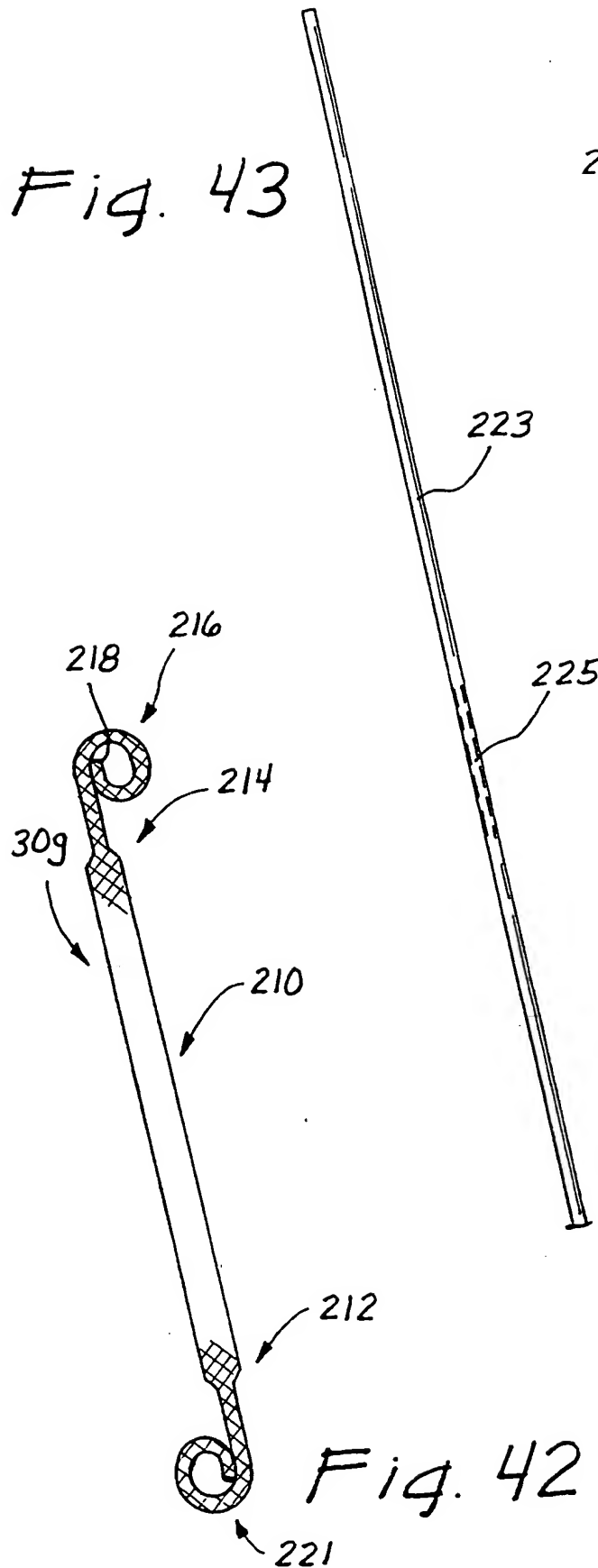


Fig. 44

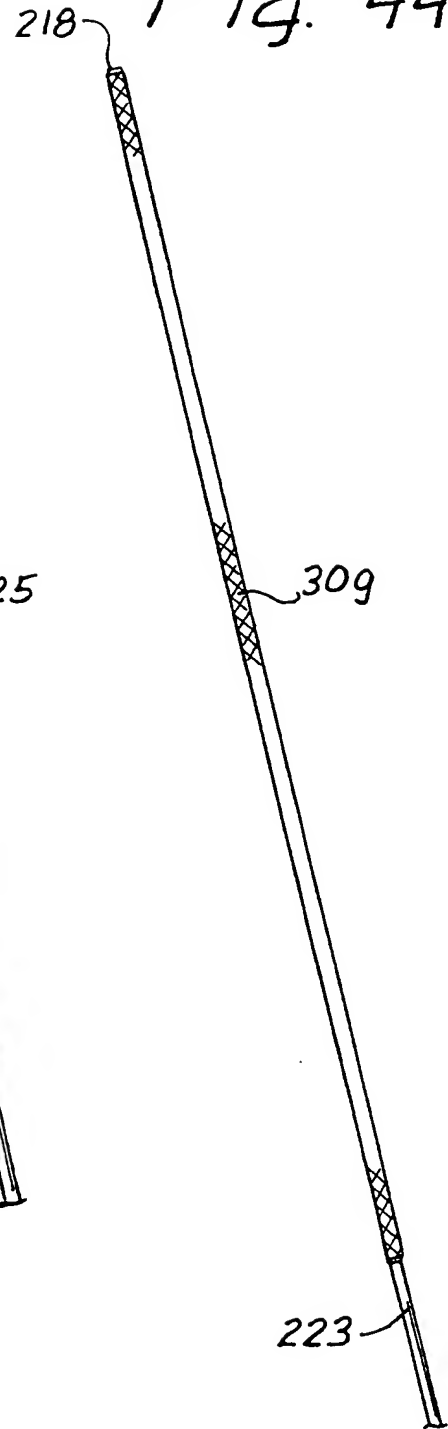
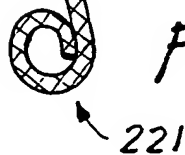


Fig. 42



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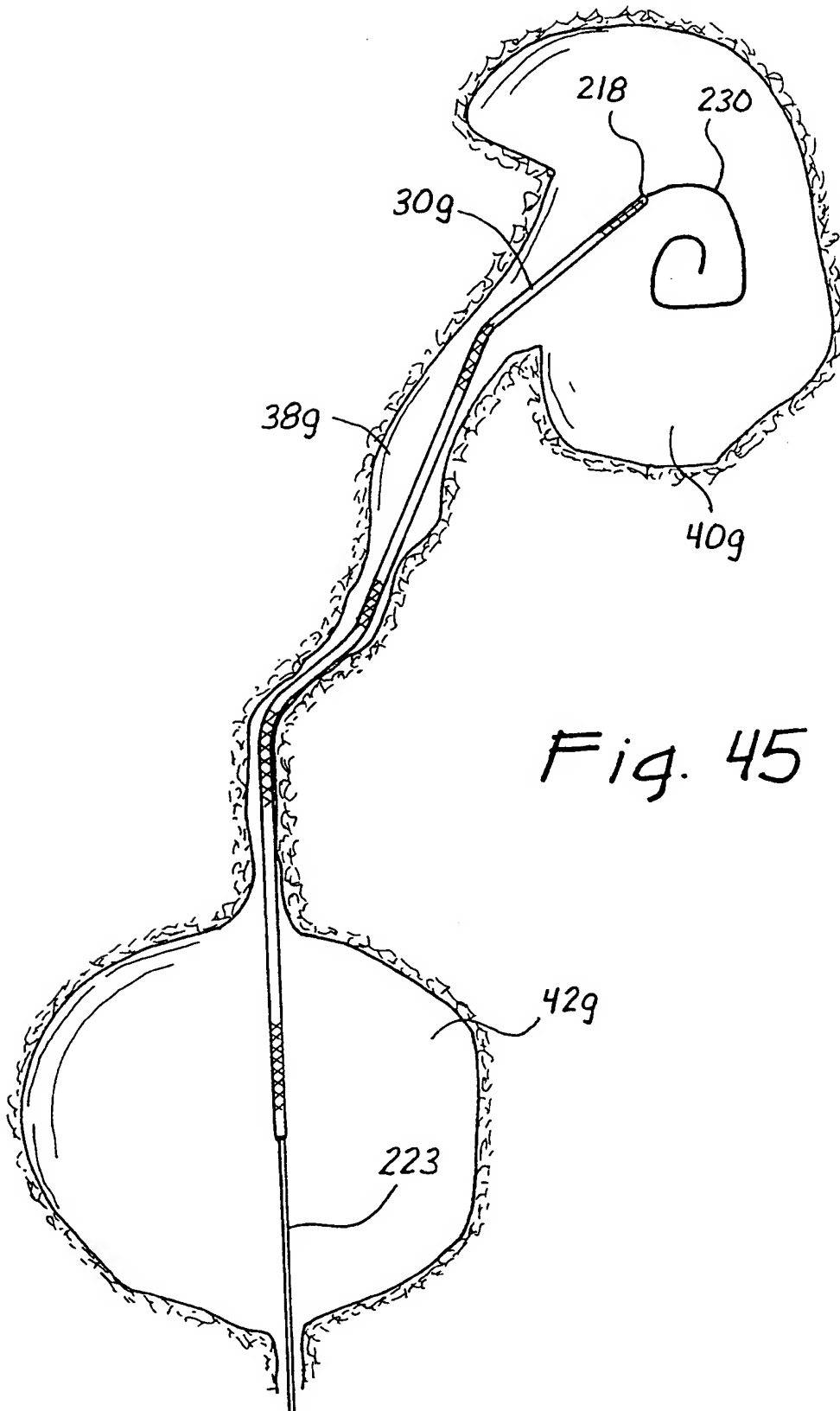
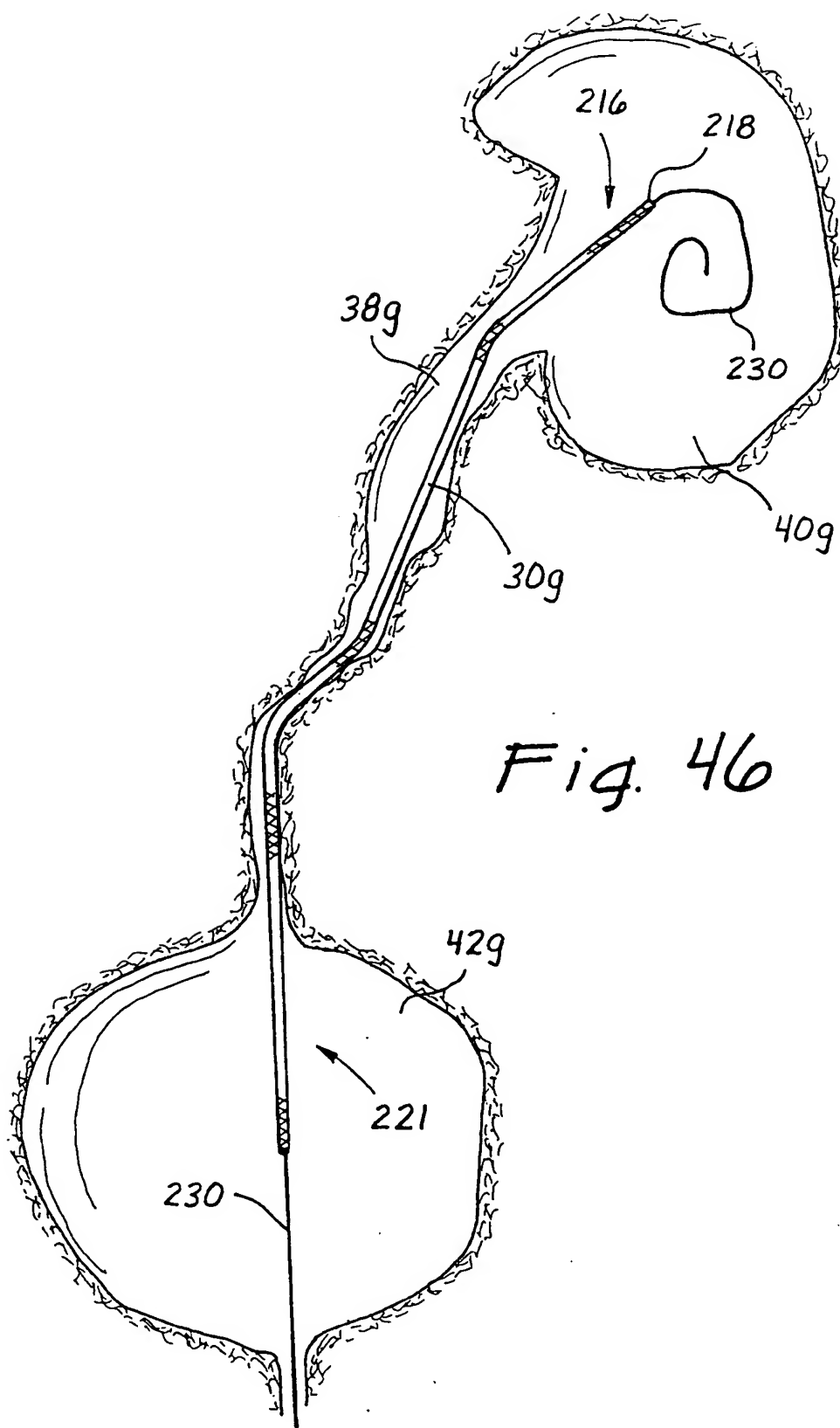


Fig. 45

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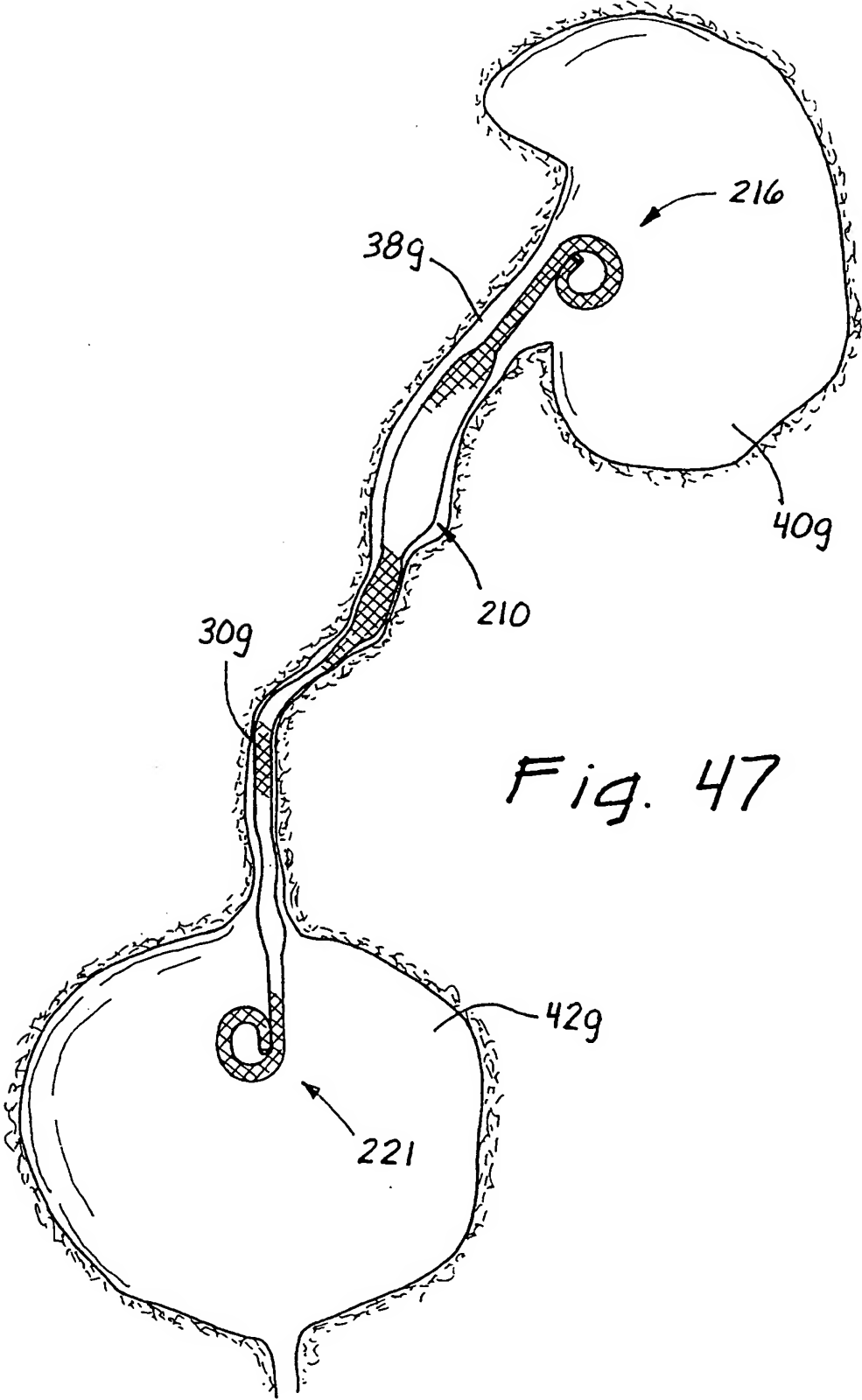


Fig. 47

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Fig. 49

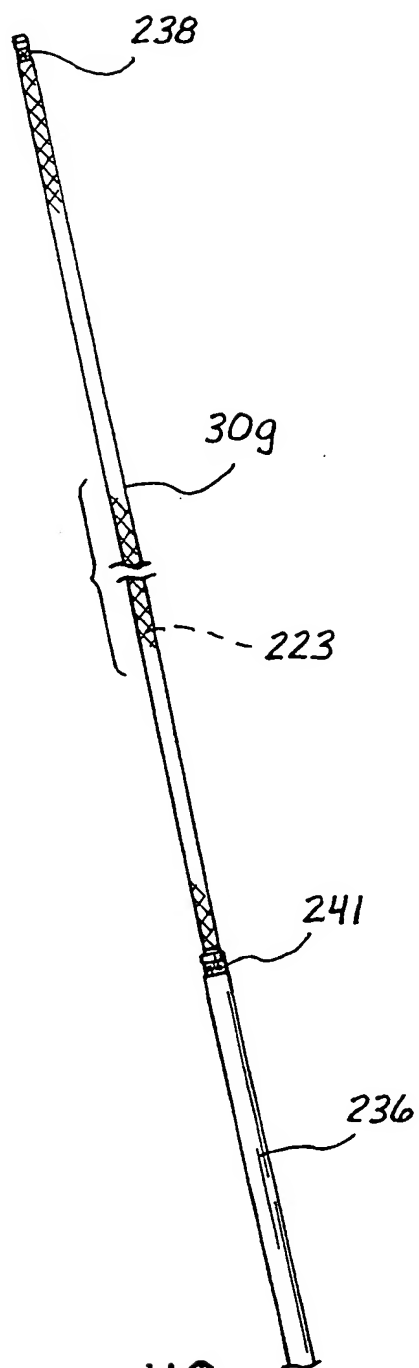
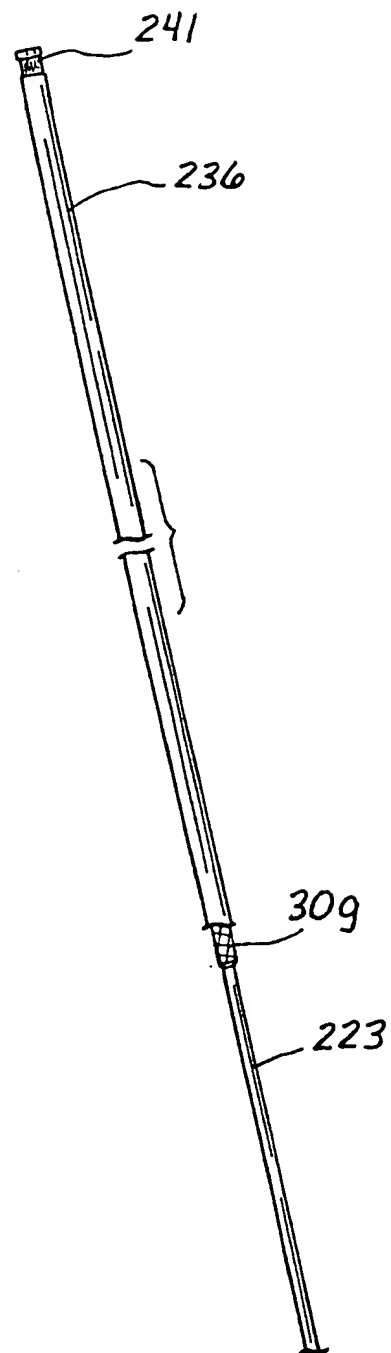


Fig. 48





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Fig. 50

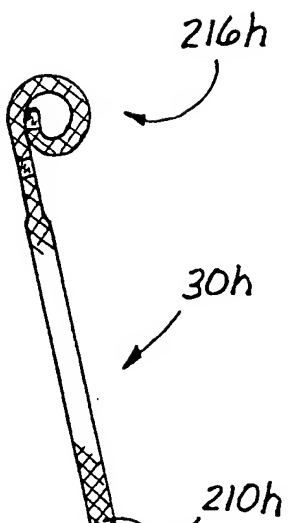
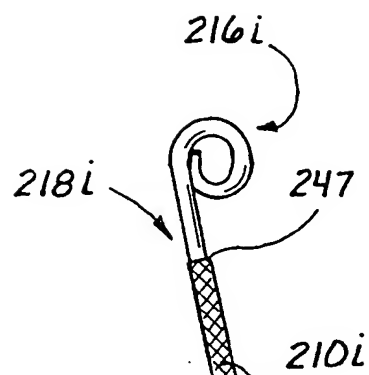
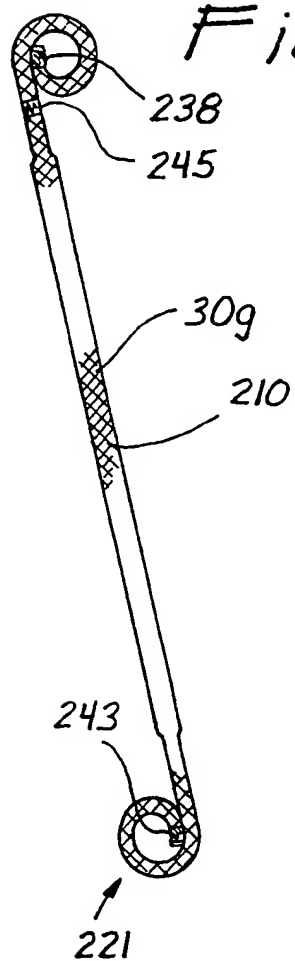


Fig. 52

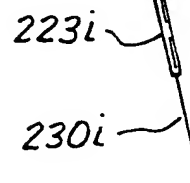
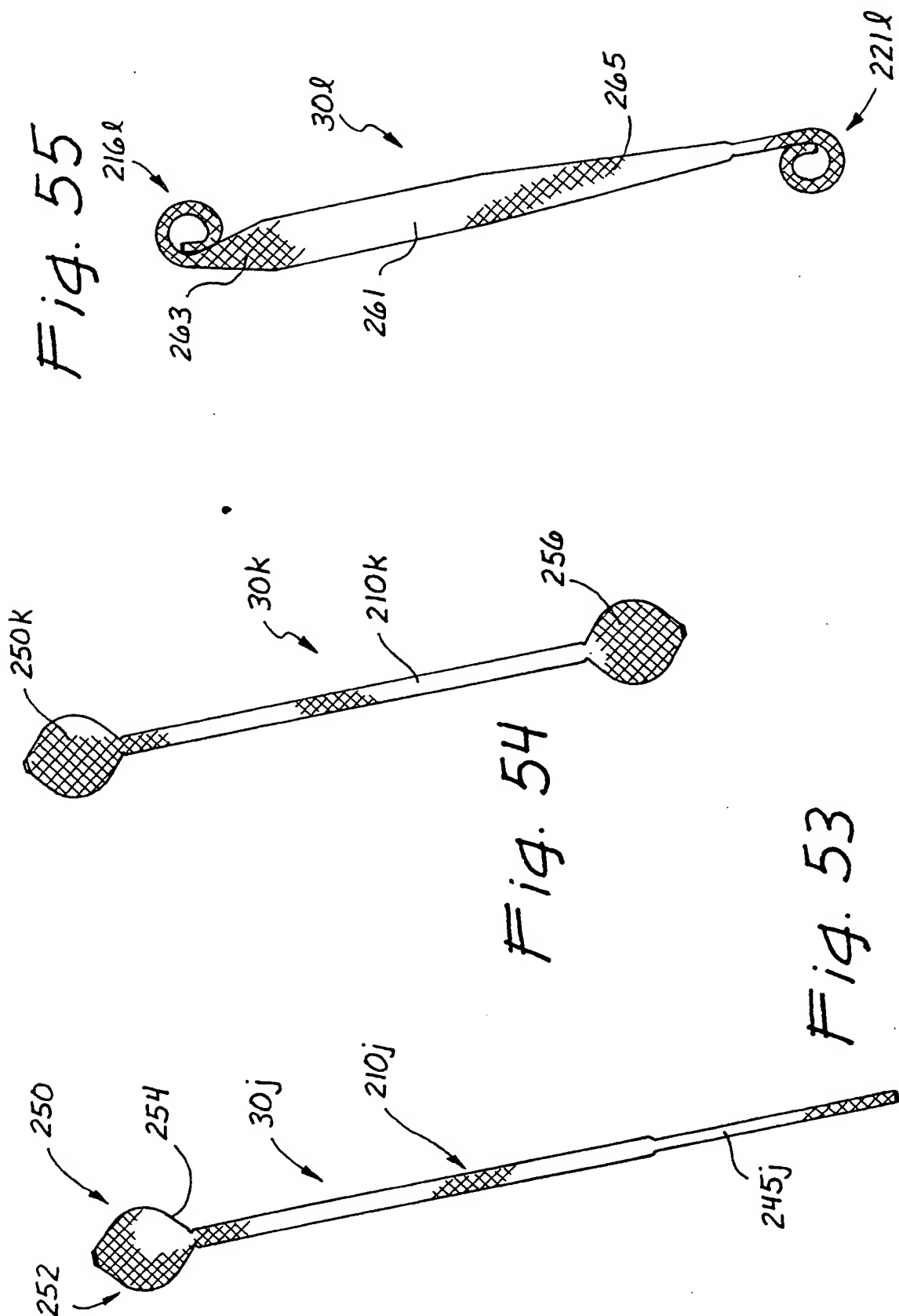


Fig. 51

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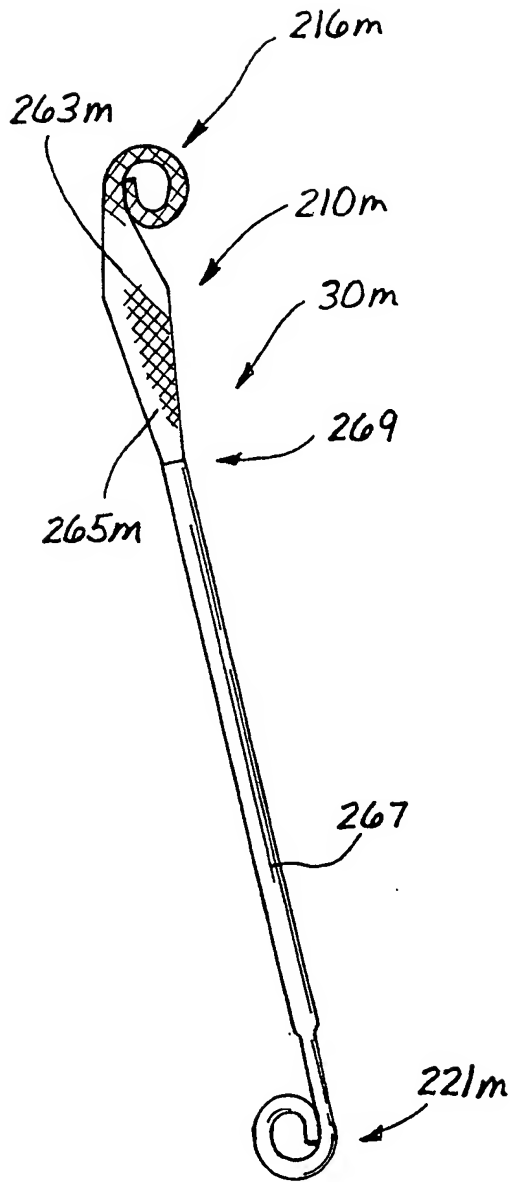
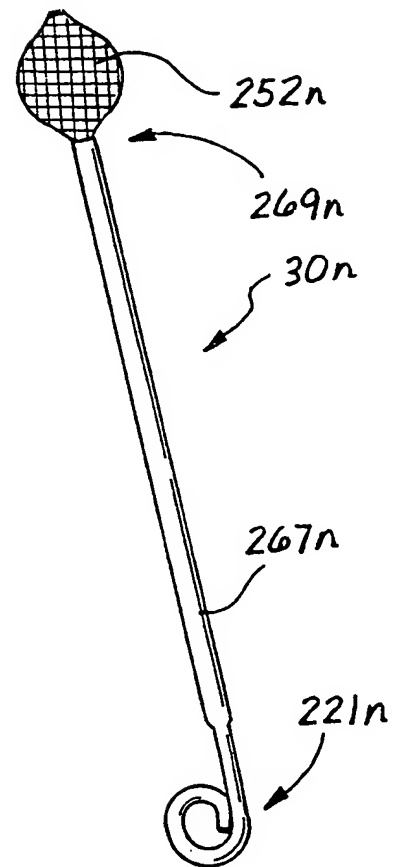
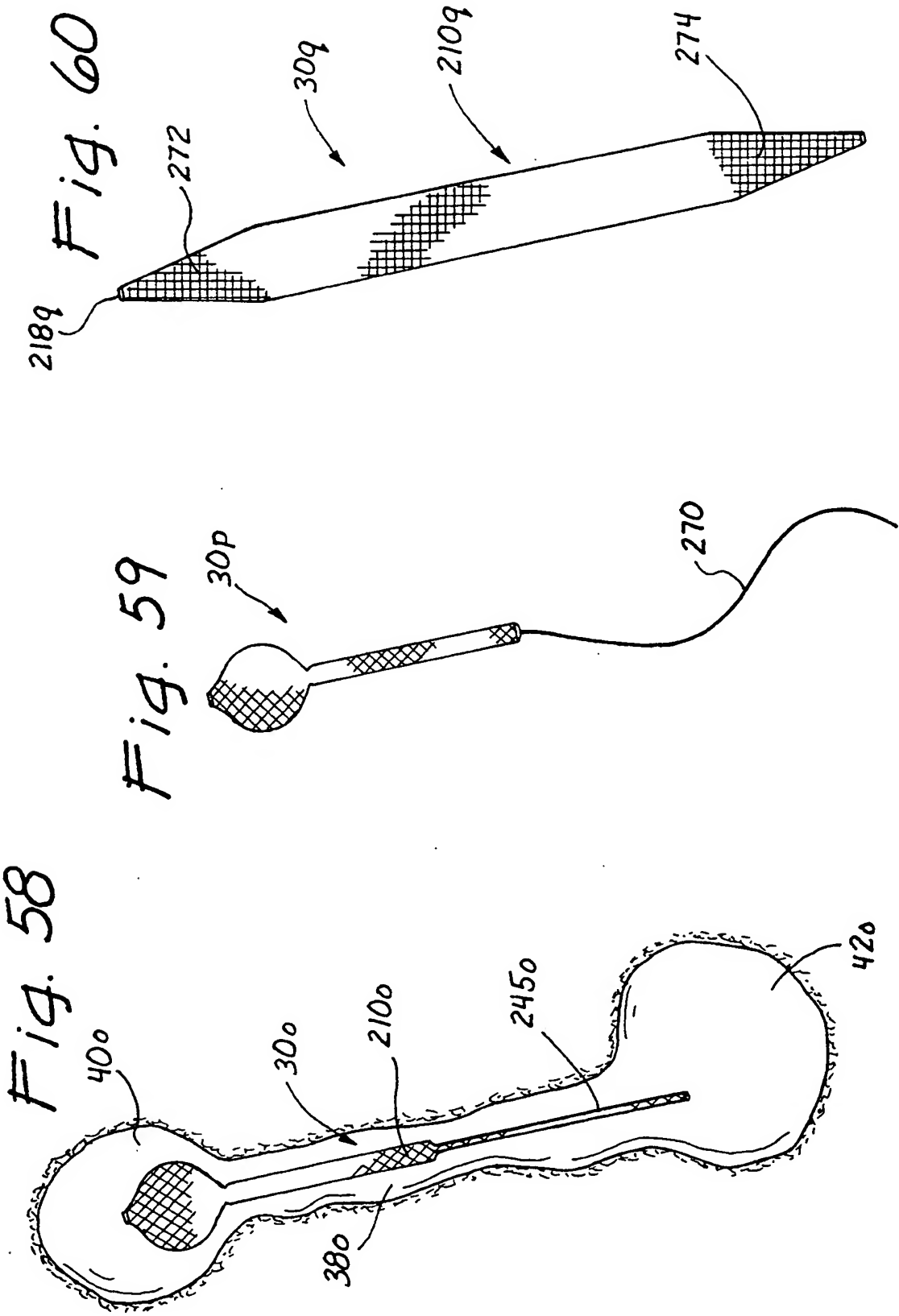


Fig. 56

Fig. 57





## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/11380

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61F 2/04

US CL :623/1.11, 1.2

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/191, 195, 198, 200; 623/1.11, 1.2, 1.12, 1.15

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,041,093 A (CHU) 20 August 1991, entire document.	1-13
X	US 5,575,818 A (PINCHUK) 19 November 1996, entire document.	14-18
X	US 4,655,771 A (WALLSTEN) 07 April 1987, entire document.	19-21, 62-67
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Y		68-77
Y	US 5,222,971 A (WILLARD et al.) 29 June 1993, entire document.	68-77
X	US 5,246,445 A (YACHIA et al.) 21 September 1993, entire document.	22-42, 93-95
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Y		83-92

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
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Date of the actual completion of the international search

16 JUNE 2000

Date of mailing of the international search report

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/11380

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,466,242 A (MORI) 14 November 1995, entire document.	43-61, 78, 79 ----- 80-92
Y	US 4,787,884 A (GOLDBERG) 29 November 1988, entire document.	80-92

A System and Method for Anti-Theft Protection of  
Information Storage Media *by Guttadauro*  
Serial No.: Not yet assigned  
Atty Docket No.: SEC-001PR (8986/P09148)  
Atty/Agent: RVDonahoe (617) 310-8411  
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